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HOUSE BILL 1528

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State of Washington                      63rd Legislature                      2013 Regular Session

By Representatives Cody, Harris, Morrell, and Ryu

Read first time 01/29/13. Referred to Committee on Health Care & Wellness.

1            AN ACT Relating to the prescription of biological products and  
2 interchangeable biosimilar products; amending RCW 69.41.010, 69.41.120,  
3 and 69.41.190; and adding a new section to chapter 69.41 RCW.

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

5            **Sec. 1.** RCW 69.41.010 and 2012 c 10 s 44 are each amended to read  
6 as follows:

7            As used in this chapter, the following terms have the meanings  
8 indicated unless the context clearly requires otherwise:

9            (1) "Administer" means the direct application of a legend drug  
10 whether by injection, inhalation, ingestion, or any other means, to the  
11 body of a patient or research subject by:

12            (a) A practitioner; or

13            (b) The patient or research subject at the direction of the  
14 practitioner.

15            (2) "Community-based care settings" include: Community residential  
16 programs for the developmentally disabled, certified by the department  
17 of social and health services under chapter 71A.12 RCW; adult family  
18 homes licensed under chapter 70.128 RCW; and assisted living facilities

1 licensed under chapter 18.20 RCW. Community-based care settings do not  
2 include acute care or skilled nursing facilities.

3 (3) "Deliver" or "delivery" means the actual, constructive, or  
4 attempted transfer from one person to another of a legend drug, whether  
5 or not there is an agency relationship.

6 (4) "Department" means the department of health.

7 (5) "Dispense" means the interpretation of a prescription or order  
8 for a legend drug and, pursuant to that prescription or order, the  
9 proper selection, measuring, compounding, labeling, or packaging  
10 necessary to prepare that prescription or order for delivery.

11 (6) "Dispenser" means a practitioner who dispenses.

12 (7) "Distribute" means to deliver other than by administering or  
13 dispensing a legend drug.

14 (8) "Distributor" means a person who distributes.

15 (9) "Drug" means:

16 (a) Substances recognized as drugs in the official United States  
17 pharmacopoeia, official homeopathic pharmacopoeia of the United States,  
18 or official national formulary, or any supplement to any of them;

19 (b) Substances intended for use in the diagnosis, cure, mitigation,  
20 treatment, or prevention of disease in human beings or animals;

21 (c) Substances (other than food, minerals or vitamins) intended to  
22 affect the structure or any function of the body of human beings or  
23 animals; and

24 (d) Substances intended for use as a component of any article  
25 specified in (a), (b), or (c) of this subsection. It does not include  
26 devices or their components, parts, or accessories.

27 (10) "Electronic communication of prescription information" means  
28 the communication of prescription information by computer, or the  
29 transmission of an exact visual image of a prescription by facsimile,  
30 or other electronic means for original prescription information or  
31 prescription refill information for a legend drug between an authorized  
32 practitioner and a pharmacy or the transfer of prescription information  
33 for a legend drug from one pharmacy to another pharmacy.

34 (11) "In-home care settings" include an individual's place of  
35 temporary and permanent residence, but does not include acute care or  
36 skilled nursing facilities, and does not include community-based care  
37 settings.

1 (12) "Legend drugs" means any drugs which are required by state law  
2 or regulation of the state board of pharmacy to be dispensed on  
3 prescription only or are restricted to use by practitioners only.

4 (13) "Legible prescription" means a prescription or medication  
5 order issued by a practitioner that is capable of being read and  
6 understood by the pharmacist filling the prescription or the nurse or  
7 other practitioner implementing the medication order. A prescription  
8 must be hand printed, typewritten, or electronically generated.

9 (14) "Medication assistance" means assistance rendered by a  
10 nonpractitioner to an individual residing in a community-based care  
11 setting or in-home care setting to facilitate the individual's self-  
12 administration of a legend drug or controlled substance. It includes  
13 reminding or coaching the individual, handing the medication container  
14 to the individual, opening the individual's medication container, using  
15 an enabler, or placing the medication in the individual's hand, and  
16 such other means of medication assistance as defined by rule adopted by  
17 the department. A nonpractitioner may help in the preparation of  
18 legend drugs or controlled substances for self-administration where a  
19 practitioner has determined and communicated orally or by written  
20 direction that such medication preparation assistance is necessary and  
21 appropriate. Medication assistance shall not include assistance with  
22 intravenous medications or injectable medications, except prefilled  
23 insulin syringes.

24 (15) "Person" means individual, corporation, government or  
25 governmental subdivision or agency, business trust, estate, trust,  
26 partnership or association, or any other legal entity.

27 (16) "Practitioner" means:

28 (a) A physician under chapter 18.71 RCW, an osteopathic physician  
29 or an osteopathic physician and surgeon under chapter 18.57 RCW, a  
30 dentist under chapter 18.32 RCW, a podiatric physician and surgeon  
31 under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a  
32 registered nurse, advanced registered nurse practitioner, or licensed  
33 practical nurse under chapter 18.79 RCW, an optometrist under chapter  
34 18.53 RCW who is certified by the optometry board under RCW 18.53.010,  
35 an osteopathic physician assistant under chapter 18.57A RCW, a  
36 physician assistant under chapter 18.71A RCW, a naturopath licensed  
37 under chapter 18.36A RCW, a pharmacist under chapter 18.64 RCW, or,

1 when acting under the required supervision of a dentist licensed under  
2 chapter 18.32 RCW, a dental hygienist licensed under chapter 18.29 RCW;

3 (b) A pharmacy, hospital, or other institution licensed,  
4 registered, or otherwise permitted to distribute, dispense, conduct  
5 research with respect to, or to administer a legend drug in the course  
6 of professional practice or research in this state; and

7 (c) A physician licensed to practice medicine and surgery or a  
8 physician licensed to practice osteopathic medicine and surgery in any  
9 state, or province of Canada, which shares a common border with the  
10 state of Washington.

11 (17) "Secretary" means the secretary of health or the secretary's  
12 designee.

13 (18) "Biological product" has the same meaning as provided in 42  
14 U.S.C. Sec. 262(i)(1), and means any of the following, when applied to  
15 the prevention, treatment, or cure of a disease or condition of human  
16 beings:

17 (a) A virus;

18 (b) A therapeutic serum;

19 (c) A toxin;

20 (d) An antitoxin;

21 (e) A vaccine;

22 (f) Blood;

23 (g) An allergenic product;

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

26 (i) Arsphenamine, a derivative of arsphenamine, or any trivalent  
27 organic arsenic compound.

28 (19) "Biosimilar product" means a biological product licensed by  
29 the federal food and drug administration pursuant to 42 U.S.C. Sec.  
30 262(k)(3)(A)(i).

31 (20) "Interchangeable" means, in reference to a biological product,  
32 that the federal food and drug administration has determined that a  
33 biosimilar product meets the safety standards set forth in 42 U.S.C.  
34 Sec. 262(k)(4).

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

37 Every drug or biological product prescription shall contain an

1 instruction on whether or not a therapeutically equivalent generic drug  
2 or interchangeable biosimilar product may be substituted in its place,  
3 unless substitution 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 biosimilar 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 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 biosimilar  
21 product may be substituted in its place. The pharmacist shall note the  
22 instructions on the file copy of the prescription.

23 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 dispensed or, if an interchangeable biosimilar  
26 product is dispensed, the brand name or, if there is not a brand name,  
27 the nonproprietary name, the strength, and the name of the manufacturer  
28 or distributor of the product.

29 The pharmacist shall retain the file copy of a written or oral  
30 prescription for at least the same period of time specified in RCW  
31 18.64.245 for retention of prescription records.

32 **Sec. 3.** RCW 69.41.190 and 2011 1st sp.s. c 15 s 80 are each  
33 amended to read as follows:

34 (1)(a)(i) Except as provided in subsection (2) of this section, any  
35 pharmacist filling a prescription under a state purchased health care  
36 program as defined in RCW 41.05.011(~~(+2)~~) (21) shall substitute, where  
37 identified, a preferred drug or biological product for any nonpreferred

1 drug or biological product in a given therapeutic class, unless the  
2 endorsing practitioner has indicated on the prescription that the  
3 nonpreferred drug or biological product must be dispensed as written,  
4 or the prescription is for a refill of an antipsychotic,  
5 antidepressant, antiepileptic, chemotherapy, antiretroviral, or  
6 immunosuppressive drug, or for the refill of a  
7 immunomodulator/antiviral treatment for hepatitis C for which an  
8 established, fixed duration of therapy is prescribed for at least  
9 twenty-four weeks but no more than forty-eight weeks, in which case the  
10 pharmacist shall dispense the prescribed nonpreferred drug or  
11 biological product.

12 (ii) In the case of a biological product, any pharmacist filling a  
13 prescription for a specific biological product may substitute a  
14 biosimilar product for the prescribed biological product only if the  
15 federal food and drug administration has determined that the biosimilar  
16 product is interchangeable with the prescribed biological product.

17 (b) When a substitution is made under (a) of this subsection, the  
18 dispensing pharmacist shall notify the prescribing practitioner of the  
19 specific drug and dose dispensed.

20 (c) If a pharmacist dispenses an interchangeable biosimilar product  
21 that is not the biological product prescribed, the pharmacist shall  
22 notify the patient or the patient's representative and the prescribing  
23 practitioner. The notification to the prescribing practitioner must:

24 (i) Be transmitted in writing or electronically;

25 (ii) Identify the brand name or, if there is not a brand name, the  
26 nonproprietary name, strength, and manufacturer or distributor of the  
27 interchangeable biosimilar product dispensed to the patient; and

28 (iii) Be transmitted to the prescribing practitioner not later than  
29 the third day after the date the interchangeable biosimilar product is  
30 dispensed.

31 (2)(a) A state purchased health care program may impose limited  
32 restrictions on an endorsing practitioner's authority to write a  
33 prescription to dispense as written only under the following  
34 circumstances:

35 (i) There is statistical or clear data demonstrating the endorsing  
36 practitioner's frequency of prescribing dispensed as written for  
37 nonpreferred drugs or biological products varies significantly from the  
38 prescribing patterns of his or her peers;

1 (ii) The medical director of a state purchased health program has:  
2 (A) Presented the endorsing practitioner with data that indicates the  
3 endorsing practitioner's prescribing patterns vary significantly from  
4 his or her peers, (B) provided the endorsing practitioner an  
5 opportunity to explain the variation in his or her prescribing patterns  
6 to those of his or her peers, and (C) if the variation in prescribing  
7 patterns cannot be explained, provided the endorsing practitioner  
8 sufficient time to change his or her prescribing patterns to align with  
9 those of his or her peers; and

10 (iii) The restrictions imposed under (~~(a)~~) this subsection  
11 (2)(a) must be limited to the extent possible to reduce variation in  
12 prescribing patterns and shall remain in effect only until such time as  
13 the endorsing practitioner can demonstrate a reduction in variation in  
14 line with his or her peers.

15 (b) A state purchased health care program may immediately designate  
16 an available, less expensive, equally effective generic product in a  
17 previously reviewed drug class as a preferred drug, without first  
18 submitting the product to review by the pharmacy and therapeutics  
19 committee established pursuant to RCW 70.14.050.

20 (c) For a patient's first course of treatment within a therapeutic  
21 class of drugs or biological products, a state purchased health care  
22 program may impose limited restrictions on endorsing practitioners'  
23 authority to write a prescription to dispense as written, only under  
24 the following circumstances:

25 (i) There is a less expensive, equally effective therapeutic  
26 alternative generic product or interchangeable biosimilar product  
27 available to treat the condition;

28 (ii) The drug use review board established under WAC 388-530-4000  
29 reviews and provides recommendations as to the appropriateness of the  
30 limitation;

31 (iii) Notwithstanding the limitation set forth in (c)(ii) of this  
32 subsection (2), the endorsing practitioner shall have an opportunity to  
33 request as medically necessary, that the brand name drug or biological  
34 product be prescribed as the first course of treatment;

35 (iv) The state purchased health care program may provide, where  
36 available, prescription, emergency room, diagnosis, and hospitalization  
37 history with the endorsing practitioner; and

1 (v) Specifically for antipsychotic restrictions, the state  
2 purchased health care program shall effectively guide good practice  
3 without interfering with the timeliness of clinical decision making.  
4 Health care authority prior authorization programs must provide for  
5 responses within twenty-four hours and at least a seventy-two hour  
6 emergency supply of the requested drug or biological product.

7 (d) If, within a therapeutic class, there is an equally effective  
8 therapeutic alternative over-the-counter drug available, a state  
9 purchased health care program may designate the over-the-counter drug  
10 as the preferred drug.

11 (e) A state purchased health care program may impose limited  
12 restrictions on endorsing practitioners' authority to prescribe  
13 pharmaceuticals to be dispensed as written for a purpose outside the  
14 scope of their approved labels only under the following circumstances:

15 (i) There is a less expensive, equally effective on-label product  
16 available to treat the condition;

17 (ii) The drug use review board established under WAC 388-530-4000  
18 reviews and provides recommendations as to the appropriateness of the  
19 limitation; and

20 (iii) Notwithstanding the limitation set forth in (e)(ii) of this  
21 subsection (2), the endorsing practitioner shall have an opportunity to  
22 request as medically necessary, that the drug or biological product be  
23 prescribed for a covered off-label purpose.

24 (f) The provisions of this subsection related to the definition of  
25 medically necessary, prior authorization procedures and patient appeal  
26 rights shall be implemented in a manner consistent with applicable  
27 federal and state law.

28 (3) Notwithstanding the limitations in subsection (2) of this  
29 section, for refills for an antipsychotic, antidepressant,  
30 antiepileptic, chemotherapy, antiretroviral, or immunosuppressive drug,  
31 or for the refill of an immunomodulator antiviral treatment for  
32 hepatitis C for which an established, fixed duration of therapy is  
33 prescribed for at least twenty-four weeks by no more than forty-eight  
34 weeks, the pharmacist shall dispense the prescribed nonpreferred drug  
35 or biological product.

36 (4) If the federal food and drug administration makes available a  
37 current list of biosimilar products determined by the federal food and

1 drug administration to be interchangeable with specific biological  
2 products, the state board of pharmacy shall maintain on its web site a  
3 link to the list.

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

6 If a pharmacist fills a prescription not covered under a state  
7 purchased health care program, the following apply:

8 (1) If a pharmacist dispenses an interchangeable biosimilar product  
9 that is not the biological product prescribed, the pharmacist shall  
10 notify the patient or the patient's representative and the prescribing  
11 practitioner. The notification to the prescribing practitioner must:

12 (a) Be transmitted in writing or electronically;

13 (b) Identify the brand name or, if there is not a brand name, the  
14 nonproprietary name, strength, and manufacturer or distributor of the  
15 interchangeable biosimilar product dispensed to the patient; and

16 (c) Be transmitted to the prescribing practitioner not later than  
17 the third day after the date the interchangeable biosimilar product is  
18 dispensed.

19 (2) A pharmacist who selects an interchangeable biosimilar product  
20 to be dispensed under this section assumes the same responsibility for  
21 selecting the interchangeable biosimilar product as the pharmacist does  
22 in filling a prescription for the interchangeable biosimilar product  
23 when prescribed by name. The prescribing practitioner is not liable  
24 for a pharmacist's act or omission in selecting, preparing, or  
25 dispensing an interchangeable biosimilar product under this section.

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