

**PROPOSED AMENDMENTS TO  
HOUSE BILL 4110**

1 On page 1 of the printed bill, line 2, delete the period and insert “; cre-  
2 ating new provisions; and amending ORS 689.522.”.

3 On page 2, after line 7, insert:

4 **“SECTION 3.** ORS 689.522 is amended to read:

5 “689.522. (1) As used in this section:

6 “(a) ‘Biological product’ means, with respect to the prevention, treatment  
7 or cure of a disease or condition of human beings, a virus, therapeutic serum,  
8 toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic  
9 product, protein other than a chemically synthesized polypeptide, analogous  
10 products or arsphenamine or any other trivalent organic arsenic compound.

11 “(b) ‘Biosimilar product’ means a biological product **that is:**

12 “(A) Licensed by the United States Food and Drug Administration pur-  
13 suant to 42 U.S.C. 262(k)(3)(A)(i); **or**

14 **“(B) Highly similar to a prescribed biological product and has been**  
15 **approved by the United States Food and Drug Administration based**  
16 **on an application filed under 21 U.S.C. 355(b)(2).**

17 “(c) ‘Interchangeable’ means[,]:

18 “(A) In reference to a biological product, that the United States Food and  
19 Drug Administration has determined that a biosimilar product meets the  
20 safety standards set forth in 42 U.S.C. 262(k)(4); **or**

21 **“(B) In reference to a biological product described in subparagraph**  
22 **(b)(B) of this subsection, that the United States Food and Drug Ad-**

1 **ministration has designated the product as therapeutically equivalent,**  
2 **under 21 U.S.C. 355, in the list of approved drug products with**  
3 **therapeutic evaluations.**

4 “(d) ‘Reference biological product’ means the biological product licensed  
5 pursuant to 42 U.S.C. 262(a) against which a biological product is evaluated  
6 in an application submitted to the United States Food and Drug Adminis-  
7 tration for licensure of a biological product as a biosimilar product or for  
8 determination that a biosimilar product is interchangeable.

9 “(2) A pharmacy or pharmacist filling a prescription order for a biological  
10 product may not substitute a biosimilar product for the prescribed biological  
11 product unless:

12 “(a) The biosimilar product has been determined by the United States  
13 Food and Drug Administration to be interchangeable with the prescribed  
14 biological product;

15 “(b) The prescribing practitioner has not designated on the prescription  
16 that substitution is prohibited;

17 “(c) The patient for whom the biological product is prescribed is informed  
18 of the substitution prior to dispensing the biosimilar product;

19 “(d) The pharmacy or pharmacist provides written, electronic or tele-  
20 phonic notification of the substitution to the prescribing practitioner or the  
21 prescribing practitioner’s staff within three business days of dispensing the  
22 biosimilar product; and

23 “(e) The pharmacy or pharmacist retains a record of the substitution for  
24 a period of not less than three years.

25 “(3) The State Board of Pharmacy shall post and regularly update on a  
26 website maintained by the board a list of biosimilar products determined by  
27 the United States Food and Drug Administration to be interchangeable.

28 **“SECTION 4. ORS 689.522, as amended by section 4, chapter 342, Oregon**  
29 **Laws 2013, is amended to read:**

30 “689.522. (1) As used in this section:

1 “(a) ‘Biological product’ means, with respect to the prevention, treatment  
2 or cure of a disease or condition of human beings, a virus, therapeutic serum,  
3 toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic  
4 product, protein other than a chemically synthesized polypeptide, analogous  
5 products or arsphenamine or any other trivalent organic arsenic compound.

6 “(b) ‘Biosimilar product’ means a biological product **that is:**

7 “(A) Licensed by the United States Food and Drug Administration pur-  
8 suant to 42 U.S.C. 262(k)(3)(A)(i); **or**

9 “(B) **Highly similar to a prescribed biological product and has been**  
10 **approved by the United States Food and Drug Administration based**  
11 **on an application filed under 21 U.S.C. 355(b)(2).**

12 “(c) ‘Interchangeable’ means[,]:

13 “(A) In reference to a biological product, that the United States Food and  
14 Drug Administration has determined that a biosimilar product meets the  
15 safety standards set forth in 42 U.S.C. 262(k)(4); **or**

16 “(B) **In reference to a biological product described in subparagraph**  
17 **(b)(B) of this subsection, that the United States Food and Drug Ad-**  
18 **ministration has designated the product as therapeutically equivalent,**  
19 **under 21 U.S.C. 355, in the list of approved drug products with**  
20 **therapeutic evaluations.**

21 “(d) ‘Reference biological product’ means the biological product licensed  
22 pursuant to 42 U.S.C. 262(a) against which a biological product is evaluated  
23 in an application submitted to the United States Food and Drug Adminis-  
24 tration for licensure of a biological product as a biosimilar product or for  
25 determination that a biosimilar product is interchangeable.

26 “(2) A pharmacy or pharmacist filling a prescription order for a biological  
27 product may not substitute a biosimilar product for the prescribed biological  
28 product unless:

29 “(a) The biosimilar product has been determined by the United States  
30 Food and Drug Administration to be interchangeable with the prescribed

1 biological product;

2 “(b) The prescribing practitioner has not designated on the prescription  
3 that substitution is prohibited;

4 “(c) The patient for whom the biological product is prescribed is informed  
5 of the substitution prior to dispensing the biosimilar product; and

6 “(d) The pharmacy or pharmacist retains a record of the substitution for  
7 a period of not less than three years.

8 “(3) The State Board of Pharmacy shall post and regularly update on a  
9 website maintained by the board a list of biosimilar products determined by  
10 the United States Food and Drug Administration to be interchangeable.”.

11 In line 8, delete “3” and insert “5”.

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