

D R A F T

SUMMARY

Requires pharmacy or pharmacist that dispenses biological product to report certain information electronically or to prescribing practitioner. Provides exceptions.

Declares emergency, effective on passage.

A BILL FOR AN ACT

1
2 Relating to biological products; creating new provisions; amending ORS
3 689.522; and declaring an emergency.

4 **Be It Enacted by the People of the State of Oregon:**

5 **SECTION 1.** ORS 689.522 is amended to read:

6 689.522. *[(1) As used in this section:]*

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

12 *[(b) “Biosimilar product” means a biological product licensed by the United*
13 *States Food and Drug Administration pursuant to 42 U.S.C. 262(k)(3)(A)(i).]*

14 *[(c) “Interchangeable” means, in reference to a biological product, that the*
15 *United States Food and Drug Administration has determined that a biosimilar*
16 *product meets the safety standards set forth in 42 U.S.C. 262(k)(4).]*

17 *[(d) “Reference biological product” means the biological product licensed*
18 *pursuant to 42 U.S.C. 262(a) against which a biological product is evaluated*
19 *in an application submitted to the United States Food and Drug Adminis-*
20 *tration for licensure of a biological product as a biosimilar product or for de-*

1 *termination that a biosimilar product is interchangeable.]*

2 [(2)] (1) A pharmacy or pharmacist filling a prescription order for a bi-
3 ological product may not substitute a [*biosimilar*] **biological** product for the
4 prescribed biological product unless:

5 (a) The [*biosimilar*] **substitute biological** product has been determined
6 by the United States Food and Drug Administration to be interchangeable
7 with the prescribed biological product;

8 (b) The prescribing practitioner has not designated on the prescription
9 that substitution is prohibited;

10 (c) The patient for whom the biological product is prescribed is informed
11 of the substitution prior to dispensing the [*biosimilar*] **substitute biological**
12 product; and

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

15 (2) **Not later than five calendar days after the dispensing of a bi-**
16 **ological product, the pharmacy or pharmacist, or the pharmacist's**
17 **designee, shall communicate the specific biological product dispensed**
18 **to the patient, including the name and manufacturer of the biological**
19 **product, by making an entry into an electronic records system that**
20 **the prescribing practitioner can access electronically and that is:**

21 (a) **An interoperable electronic medical records system;**

22 (b) **An electronic prescribing technology;**

23 (c) **A pharmacy benefit management system; or**

24 (d) **A pharmacy record.**

25 (3) **If the pharmacy or pharmacist, or the pharmacist's designee,**
26 **does not have access to an electronic records system described in**
27 **subsection (2) of this section, the pharmacy or pharmacist, or the**
28 **pharmacist's designee, shall communicate not later than five calendar**
29 **days to the prescribing practitioner the specific biological product**
30 **dispensed to the patient, including the name and manufacturer of the**
31 **biological product. The communication may be by facsimile, electronic**

1 mail, telephone or another method.

2 (4) Notwithstanding subsections (2) and (3) of this section, the
3 pharmacy or pharmacist, or the pharmacist's designee, is not required
4 to communicate to the prescribing practitioner the specific biological
5 product dispensed to the patient if:

6 (a) The United States Food and Drug Administration has not ap-
7 proved an interchangeable biological product for the prescribed bi-
8 ological product; or

9 (b) The pharmacy or pharmacist is refilling a prescription and the
10 pharmacy or pharmacist is dispensing the same biological product that
11 was dispensed the last time the pharmacy or pharmacist filled or re-
12 filled the patient's prescription.

13 (5) The entry described in subsection (2) of this section or the
14 communication described in subsection (3) of this section provides
15 notice to the prescribing provider of the dispensation of a biological
16 product to a patient.

17 [(3)] (6) The State Board of Pharmacy shall, *[post and regularly update]*
18 on a website maintained by the board, **maintain a link to the current list,**
19 **if available, of biological** *[a list of biosimilar]* products determined by the
20 United States Food and Drug Administration to be interchangeable.

21 (7) For purposes of this section, the board shall adopt by rule defi-
22 nitions for the terms "biological product" and "interchangeable." The
23 rule defining the term "biological product" must be consistent with 42
24 U.S.C. 262(i)(1). The rule defining the term "interchangeable" must
25 describe biological products that may be substituted for other biolog-
26 ical products as meeting the standards in 42 U.S.C. 262(k)(4) or as be-
27 ing determined to be therapeutically equivalent by the United States
28 Food and Drug Administration as set forth in the latest edition or
29 supplement of the Approved Drug Products with Therapeutic Equiv-
30 alence Evaluations.

31 SECTION 2. ORS 689.522 does not prohibit an insurer or other

1 **health care payer from requiring prior authorization or imposing other**
2 **appropriate utilization controls in approving coverage for any biolog-**
3 **ical product.**

4 **SECTION 3. This 2016 Act being necessary for the immediate pres-**
5 **ervation of the public peace, health and safety, an emergency is de-**
6 **clared to exist, and this 2016 Act takes effect on its passage.**

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