CHAPTER 43

AN ACT HB 4105

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

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

SECTION 1. ORS 689.522 is amended to read:

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

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

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

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

[*(d) "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. 262(a) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.*]

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

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

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

(c) The patient for whom the biological product is prescribed is informed of the substitution [*prior to dispensing the biosimilar product*] **in a manner reasonable under the circumstances**; and

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

(2) Not later than five business days after the dispensing of a biological product, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, by making an entry into an electronic system that the prescribing practitioner can access electronically and that is:

(a) An interoperable electronic medical records system;

(b) An electronic prescribing technology;

(c) A pharmacy benefit management system; or

(d) A pharmacy record.

(3) If the pharmacy or pharmacist, or the pharmacist's designee, does not have access to an electronic system described in subsection (2) of this section, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate not later than five business days to the prescribing practitioner the specific biological product dispensed to the patient, including the name and manufacturer of the biological product. The communication may be by facsimile, electronic mail, telephone or another method.

(4) If the biological product is dispensed to a patient in a clinic, community-based care facility, hospital or long term care facility, an entry made to the patient's medical record of the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, satisfies the communication requirements of subsections (2) and (3) of this section.

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

(a) The United States Food and Drug Administration has not approved an interchangeable biological product for the prescribed biological product;

(b) The pharmacy or pharmacist is refilling a prescription and the pharmacy or pharmacist is dispensing the same biological product that was dispensed the last time the pharmacy or pharmacist filled or refilled the patient's prescription; or

(c) The pharmacy or pharmacist is filling a prescription for a vaccine.

(6) The entries described in subsections (2) and (4) of this section or the communication described in subsection (3) of this section provides notice to the prescribing provider of the dispensation of a biological product to a patient.

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

(8)(a) For purposes of this section, the board shall adopt by rule definitions for the terms "biological product" and "interchangeable."

(b) The rule defining the term "biological product" must be consistent with 42 U.S.C. 262(i)(1).

(c) The rule defining the term "interchangeable" must:

(A) For biological products licensed under the Public Health Service Act, define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as meeting the standards in 42 U.S.C. 262(k)(4); and

(B) For biological products approved by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as therapeutically equivalent as set forth in the latest edition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

SECTION 2. ORS 689.522, as amended by section 1 of this 2016 Act, is amended to read:

689.522. (1) A pharmacy or pharmacist filling a prescription order for a biological product may not substitute a biological product for the prescribed biological product unless:

(a) The substitute biological product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product;

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

(c) The patient for whom the biological product is prescribed is informed of the substitution in a manner reasonable under the circumstances; and

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

[*(2) Not later than five business days after the dispensing of a biological product, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, by making an entry into an electronic system that the prescribing practitioner can access electronically and that is:*]

[*(a) An interoperable electronic medical records system;*]

[*(b) An electronic prescribing technology;*]

[*(c) A pharmacy benefit management system; or*]

[*(d) A pharmacy record.*]

[*(3) If the pharmacy or pharmacist, or the pharmacist's designee, does not have access to an electronic system described in subsection (2) of this section, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate not later than five business days to the prescribing practitioner the specific biological product dispensed to the patient, including the name and manufacturer of the biological product. The communication may be by facsimile, electronic mail, telephone or another method.*]

[*(4) If the biological product is dispensed to a patient in a clinic, community-based care facility, hospital or long term care facility, an entry made to the patient's medical record of the specific biological product dispensed to the patient, including the name and manufacturer of the biological product, satisfies the communication requirements of subsections (2) and (3) of this section.*]

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

[*(a) The United States Food and Drug Administration has not approved an interchangeable biological product for the prescribed biological product;*]

[*(b) The pharmacy or pharmacist is refilling a prescription and the pharmacy or pharmacist is dispensing the same biological product that was dispensed the last time the pharmacy or pharmacist filled or refilled the patient's prescription; or*]

[*(c) The pharmacy or pharmacist is filling a prescription for a vaccine.*]

[*(6) The entries described in subsections (2) and (4) of this section or the communication described in subsection (3) of this section provides notice to the prescribing provider of the dispensation of a biological product to a patient.*]

[*(7)*] **(2)** The State Board of Pharmacy shall, on a website maintained by the board, maintain a link to the current list, if available, of biological products determined by the United States Food and Drug Administration to be interchangeable.

[*(8)(a)*] **(3)(a)** For purposes of this section, the board shall adopt by rule definitions for the terms "biological product" and "interchangeable."

(b) The rule defining the term "biological product" must be consistent with 42 U.S.C. 262(i)(1).

(c) The rule defining the term "interchangeable" must:

(A) For biological products licensed under the Public Health Service Act, define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as meeting the standards in 42 U.S.C. 262(k)(4); and

(B) For biological products approved by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 et seq., define the biological products that may be substituted for other biological products as having been determined by the United States Food and Drug Administration as therapeutically equivalent as set forth in the latest edition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

SECTION 3. The amendments to ORS 689.522 by section 2 of this 2016 Act become operative on January 2, 2022.

SECTION 4. ORS 689.522 does not prohibit an insurer or other health care payer from requiring prior authorization or imposing other

appropriate utilization controls in approving coverage for any biological product.

SECTION 5. This 2016 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2016 Act takes effect on its passage.

Approved by the Governor March 14, 2016
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