SB 147-1
(LC 1524)
2/26/15 (MBM/ps)

**PROPOSED AMENDMENTS TO**
**SENATE BILL 147**

On page 1 of the printed bill, delete lines 5 through 30.

On page 2, delete lines 1 through 24 and insert:

**"SECTION 1.** ORS 689.522, as amended by section 4, chapter 342, Oregon Laws 2013, 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*] **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*] **biological** product; and

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

"**(2)(a) Within a reasonable amount of time following the dispensing of a biological product, the pharmacy or pharmacist, or the pharmacist's designee, shall communicate to the prescribing practitioner the specific biological product dispensed to the patient, including the name and manufacturer of the biological product.**

**"(b) A communication made under paragraph (a) of this subsection must, if possible, be conveyed by making an entry in an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record that is electronically accessible by the prescribing practitioner. Otherwise, the communication must be made by telephone, facsimile, electronic transmission or other prevailing means.**

**"(c) Notwithstanding paragraph (a) of this subsection, 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 biological product prescribed; or**

**"(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 pharmacist filled or refilled the patient's prescription.**

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

"**(4) For purposes of this section and section 3 of this 2015 Act, the board shall adopt by rule definitions for the terms 'biological product' and 'interchangeable.' The rule defining the term 'biological product' must be consistent with 42 U.S.C. 262(i)(1). The rule defining the term 'interchangeable' must describe biological products that may be substituted for other biological products as meeting the standards in 42 U.S.C. 262(k)(4) or as being determined to be therapeutically equivalent by the United States Food and Drug Administration as set forth in the latest edition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.**".

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