LC 1524
2015 Regular Session
10/20/14 (MBM/ps)

D R A F T

SUMMARY

Changes communication requirements for pharmacy or pharmacist that substitutes biological product. Requires pharmacy to provide notice of potential substitution.

Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to biological products; creating new provisions; amending ORS 689.515 and 689.522; repealing section 5, chapter 342, Oregon Laws 2013; and declaring an emergency.

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

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*

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

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) Within a reasonable amount of time following the dispensing of the biological product, the pharmacy or pharmacist, or the pharmacist's designee, communicates to the prescribing practitioner the specific biological product dispensed to the patient, including the name of the biological product and the manufacturer of biological product; and

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

(2)(a) A communication made under subsection (1)(d) of this section must 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. If no such means of communication is available, the communication must be made by telephone, facsimile, electronic transmission or other prevailing means.

(b) Notwithstanding subsection (1)(d) of this section, the pharmacy or pharmacist, or the pharmacist's designee, is not required to com-

municate to the prescribing practitioner the specific biological product dispensed to the patient if 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 substituted biological products as meeting the standards in 42 U.S.C. 262(k)(4) or as being determined 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.

SECTION 2. Section 3 of this 2015 Act is added to and made a part of ORS chapter 689.

SECTION 3. A pharmacy shall post a sign, in a location easily seen by patrons at the counter where prescriptions are dispensed or administered, stating that, "This pharmacy may be able to substitute a less expensive drug or biological product that is therapeutically equivalent to or interchangeable with the one prescribed by your doctor, unless you do not approve." The printing on the sign must be in block letters not less than one inch in height. If the pharmacist has reasonable cause to believe that the purchaser cannot read the sign or comprehend its content, the pharmacist shall endeavor to explain the meaning of the sign.

SECTION 4. ORS 689.515 is amended to read:

689.515. (1) As used in this section unless the context requires otherwise:

(a) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label or wrapping at the time of packaging.

(b) "Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including but not limited to tablets, capsules, oral solutions, aerosols, ointments, inhalers and suppositories, and the particular form of which utilizes a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption or other delivery of a dosage regimen in the body.

(c) "Generic name" means the official title of a drug or drug ingredients published in the latest edition of the official Pharmacopoeia, Homeopathic Pharmacopoeia or Formulary.

(d) "Substitute" means to dispense without the prescriber's express authorization a different drug product in place of the drug ordered or prescribed.

(e) "Therapeutically equivalent" means drugs that are approved by the United States Food and Drug Administration for interstate distribution and the Food and Drug Administration has determined that the drugs will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

(2) Except as limited by subsections (3) and [*(5)*] **(4)** of this section, unless the purchaser instructs otherwise, a pharmacist may substitute as follows:

(a) A drug product with the same generic name in the same strength, quantity, dose and dosage form as the prescribed drug which is, in the pharmacist's professional opinion, therapeutically equivalent.

(b) When the prescriber is not reasonably available for consultation and the prescribed drug does not utilize a unique delivery system technology, an oral tablet, capsule or liquid form of the prescribed drug so long as the form dispensed or administered has the same strength, dose and dose schedule and is therapeutically equivalent to the drug prescribed.

(3) A practitioner may specify in writing, by a telephonic communication or by electronic transmission that there may be no substitution for the specified brand name drug in a prescription.

[*(4) A pharmacy shall post a sign in a location easily seen by patrons at the counter where prescriptions are dispensed or administered stating that, "This pharmacy may be able to substitute a less expensive drug which is therapeutically equivalent to the one prescribed by your doctor unless you do not approve." The printing on the sign must be in block letters not less than one inch in height. If the pharmacist has reasonable cause to believe that the purchaser cannot read the sign or comprehend its content, the pharmacist shall endeavor to explain the meaning of the sign.*]

[*(5)*] **(4)** A pharmacist may substitute a drug product under this section only when there will be a savings in or no increase in cost to the purchaser.

[*(6)*] **(5)** If the practitioner prescribes a drug by its generic name, the pharmacist shall, consistent with reasonable professional judgment, dispense or administer the lowest retail cost, effective brand which is in stock.

[*(7)*] **(6)** Except as provided in subsection [*(8)*] **(7)** of this section, when a pharmacist dispenses a substituted drug as authorized by subsection (2) of this section, the pharmacist shall label the prescription container with the name of the dispensed drug. If the dispensed drug does not have a brand name, the pharmacist shall label the prescription container with the generic name of the drug dispensed along with the name of the drug manufacturer.

[*(8)*] **(7)** A prescription dispensed by a pharmacist must bear upon the label the name of the medication in the container or shall be labeled as intended by the prescriber.

[*(9)*] **(8)** The substitution of any drug by a pharmacist or the pharmacist's employer pursuant to this section does not constitute the practice of medicine.

[*(10)*] **(9)** A substitution of drugs made by a pharmacist or the pharmacist's employer in accordance with this section and any rules that the State Board of Pharmacy may adopt thereunder does not constitute evidence

of negligence if the substitution was made within reasonable and prudent practice of pharmacy or if the substituted drug was accepted in a generally recognized formulary or government list.

[*(11)*] **(10)** Failure of a practitioner to specify that no substitution is authorized does not constitute evidence of negligence unless the practitioner knows that the health condition of the patient for whom the practitioner is prescribing warrants the use of the brand name drug product and not the substituted drug.

SECTION 5. Section 5, chapter 342, Oregon Laws 2013, is repealed.

SECTION 6. This 2015 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2015 Act takes effect on its passage.
