House Bill 2755

Sponsored by Representatives SALINAS, NOSSE

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure **as introduced.**

Requires pharmacy or pharmacist to substitute prescribed brand name drug with generic name drug product and to substitute prescribed biological product with interchangeable biological product.

Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to pharmaceutical substitutions; creating new provisions; amending ORS 689.515 and 689.522; and declaring an emergency.

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

SECTION 1. 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) of this section, unless the purchaser instructs otherwise, a pharmacist [*may*] **shall** 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.

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.

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

(9) 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) 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) 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 2. ORS 689.522 is amended to read:

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

(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) 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) 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. ORS 689.522, as amended by section 2, chapter 43, Oregon Laws 2016, is amended to read:

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

(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) 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.

(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 4. (1) The amendments to ORS 689.515 by section 1 of this 2019 Act apply to drug products prescribed on and after the operative date of this 2019 Act.

(2) The amendments to ORS 689.522 by sections 2 and 3 of this 2019 Act apply to biological products prescribed on and after the operative date of this 2019 Act.

SECTION 5. (1) The amendments to ORS 689.515 and 689.522 by sections 1 to 3 of this 2019 Act become operative on January 1, 2020.

(2) The State Board of Pharmacy may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the board to exercise, on and after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the board by the amendments to ORS 689.515 and 689.522 by sections 1 to 3 of this 2019 Act.

SECTION 6. This 2019 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2019 Act takes effect on its passage.