HOUSE AMENDMENTS TO HOUSE BILL 4105

By COMMITTEE ON HEALTH CARE

February 9

On page 1 of the printed bill, delete line 27 and insert "in a manner reasonable under the circumstances; and".

In line 30, delete "calendar" and insert "business".

On page 2, line 2, delete "records".

In line 9, delete "records".

In line 10, delete "calendar" and insert "business".

After line 13, insert:

"(4) If the biological product is dispensed to a patient in an assisted living facility, clinic, hospital or nursing home, an entry made to the patient's 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.".

In line 14, delete "(4)" and insert "(5)".

In line 18, delete "or".

In line 21, delete the period and insert "; or

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

In line 22, delete "(5)" and insert "(6)" and delete "entry" and insert "entries" and delete "subsection" and insert "subsections" and after "(2)" insert "and (4)".

In line 25, delete "(6)" and insert "(7)".

In line 28, delete "(7)" and insert "(8)(a)".

In line 29, after "interchangeable." begin a new paragraph and insert "(b)".

In line 30, after "42 U.S.C. 262(i)(1)." begin a new paragraph and insert "(c)".

Delete lines 31 through 35 and insert "must:

"(A) For biological products licensed under the Public Health Service Act, describe 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., describe 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 an assisted living facility, clinic, hospital or nursing home, an entry made to the patient's 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, describe 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., describe 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.**".

In line 36, delete "2" and insert "4".

In line 39, delete "3" and insert "5".