SENATE FILE NO. SF0075

Biological products-pharmacies.

Sponsored by: Senator(s) Baldwin and Boner and Representative(s) Barlow, Blackburn, Eyre, Larsen and Lindholm

A BILL

for

AN ACT relating to pharmacy; authorizing a pharmacist to dispense specified biological products as a substitute for a prescribed drug; providing definitions; requiring specified recordkeeping relating to biological products; making conforming amendments; and providing for an effective date.

*Be It Enacted by the Legislature of the State of Wyoming:*

**Section 1.** W.S. 33-24-136(a) and (e), 33-24-147(a)(iv), by creating new paragraphs (vi) and (vii) and by renumbering (vi) as (viii), 33-24-148(b), (e)(intro) and (g) and 33-24-149 are amended to read:

**33-24-136. Filing memorandum of prescription; labels generally; prescription defined; counseling and patient profiles.**

(a) Every person who prepares, compounds, processes, packages or repackages, dispenses, fills or sells or offers for sale, at retail or in connection with operation of a health care facility, any prescription, shall place the written or electronic record of the prescription in a separate file marked and kept for that purpose, and shall affix a label to the container in which the prescribed substance is dispensed bearing the name and address of the pharmacy and initials of the dispensing pharmacist, or of the preceptor if the dispenser is an intern, the date on which the prescription is filed in the pharmacy's files, the name of the person who prescribed the substance, the name of the patient or customer for whom the prescription was made and directions for use by the patient as directed on the prescription by the ~~prescriber~~ practitioner.

(e) Notwithstanding subsection (a) of this section, if, in the opinion of the pharmacist, an emergency exists whereby the ~~prescriber of~~ practitioner who ordered or

prescribed the prescription cannot be contacted for authorization and there is a need to refill the prescription, the pharmacist may provide up to a seventy-two (72) hour supply, or the smallest available unit, of the previously prescribed drug, except a controlled substance. Nothing in this subsection shall be construed to require a pharmacist to refill the prescription in the absence of authorization from the ~~prescriber~~ practitioner.

**33-24-147. Definitions.**

(a) As used in this act:

(iv) "Substitute" means to dispense a generically equivalent drug or interchangeable biological product in place of the ~~dangerous substance~~ prescription ordered or prescribed;

(vi) "Biological product" means as defined in 42 U.S.C. 262(i)(1);

(vii) "Interchangeable biological product" means a biological product that the United States food and drug administration has:

(A) Licensed and determined meets the standards for interchangeability under 42 U.S.C. 262(k)(4); or

(B) Determined is therapeutically equivalent to the prescription ordered or prescribed, as set forth in the latest edition or supplement to the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) issued by the United States food and drug administration.

~~(vi)~~ (viii) "This act" means W.S. 33-24-146 through 33-24-151.

**33-24-148. Conditions for drug substitution.**

(b) Except as limited by W.S. 33-24-149(b) or when the practitioner has clearly indicated substitution is not permitted, a pharmacist may substitute:

(i) A drug product with the same generic name in the identical strength, quantity, dose and dosage form as the prescribed drug, provided the substituted product or drug meets all requirements specified in W.S. 33-24-147(a)(ii);~~.~~

(ii) An interchangeable biological product.

(e) A pharmacist may not substitute a generically equivalent drug ~~product~~ unless it has been manufactured with the following minimum manufacturing standards and practices by a manufacturer who:

(g) When a practitioner orally communicates a prescription and prohibits ~~a generic~~ substitution of an interchangeable biological product or generically equivalent drug, the pharmacist shall make reasonable efforts to obtain a written prescription from the practitioner with the phrase "brand medically necessary" written on the face of the prescription in his own handwriting.

**33-24-149. Drug substitution procedures.**

(a) A pharmacist who receives a prescription for a brand name prescription drug may dispense any interchangeable biological product or generically equivalent drug of the brand name prescription drug prescribed, unless the prescribing practitioner has clearly indicated substitution is not permitted.

(b) If a practitioner prescribes a prescription drug by its generic name or by the nonproprietary name of an interchangeable biological product, the pharmacist may dispense the generically equivalent drug or the interchangeable biological product as defined in this act.

(c) Except as provided in subsection (e) of this section, when a pharmacist dispenses ~~a substituted drug~~ an interchangeable biological product or generically equivalent drug as authorized by this act, he shall label the prescription container with the name of the dispensed biological product or drug. If the dispensed drug or product does not have a brand name, the prescription label shall indicate the generic name of the drug dispensed or

the nonproprietary name of the interchangeable biological product dispensed.

(d) The national drug code number or the name of the manufacturer or distributor of the ~~generic drug~~ interchangeable biological product or generically equivalent drug dispensed shall be noted on the prescription record or entry by the pharmacist.

(e) A prescription dispensed by a pharmacist shall bear upon the label the name of the medication in the container except if the ~~prescriber~~ practitioner orders "do not label", or words of similar import, on the prescription or so designates in an oral or electronic transmission of the prescription.

(f) Except as otherwise provided in subsections (g) and (j) of this section, not later than five (5) business days after dispensing a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product dispensed to the patient, including the name and manufacturer of the product. The entry shall

be electronically accessible to the practitioner through one (1) of the following electronic records systems:

(i) An interoperable electronic medical records system;

(ii) Electronic prescribing technology;

(iii) A pharmacy benefit management system; or

(iv) A pharmacy record.

(g) Except as otherwise provided in subsection (j) of this section, if an electronic records system under subsection (f) of this section is not available, the dispensing pharmacist shall, not later than five (5) business days after dispensing a biological product, communicate to the practitioner the specific product dispensed to the patient, including the name and manufacturer of the product, using facsimile, telephone, electronic transmission or any other prevailing means of communication.

(h) An entry made into an electronic records system under subsection (f) of this section or a communication made under subsection (g) of this section shall establish a presumption that the practitioner received notice of the biological product dispensed to the patient.

(j) The requirements of subsections (f) and (g) of this section shall not apply if:

(i) There is no interchangeable biological product for the product prescribed by the practitioner; or

(ii) A prescription for a refill is not changed from the product dispensed on the prior filling of the prescription.

(k) The dispensing pharmacist shall notify a patient of the biological product which was dispensed, which may be carried out through the prescription label required pursuant subsection (c) of this section.

**Section 2.** This act is effective July 1, 2018.

(END)