HOUSE BILL NO. 233

INTRODUCED BY R. EHLI, M. BLASDEL, E. BUTTREY, J. COHENOUR, K. MCCARTHY, M. MCNALLY, F. THOMAS, R. WEBB

A BILL FOR AN ACT ENTITLED: "AN ACT REVISING DRUG PRODUCT SELECTION LAWS TO INCLUDE BIOLOGICAL PRODUCTS; PROVIDING DEFINITIONS; REQUIRING REPORTING OF DRUG PRODUCT SELECTION; AND AMENDING SECTIONS 37-7-502, 37-7-504, AND 37-7-505, MCA."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

Section 1. Section 37-7-502, MCA, is amended to read:

"37-7-502. Definitions. As used in this part, the following definitions apply:

(1) "Bioavailability" means the extent and rate of absorption from a dosage form as reflected by the time-concentration curve of the administered drug in the systemic circulation.

(2) "Bioequivalent" means a chemical equivalent which, when administered to the same individual in the same dosage regimen, will result in comparable bioavailability.

(3) "Biological product" has the meaning provided in 42 U.S.C. 262.

~~(3)~~(4) "Brand name" means the proprietary or the registered trademark name given to a drug product by its manufacturer, labeler, or distributor and placed upon the drug, its container, label, or wrapping at the time of packaging.

~~(4)~~(5) "Chemical equivalent" means drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage forms and that meet present compendium standards.

~~(5)~~(6) "Drug product" means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process. ~~The term includes a biological product.~~

~~(6)~~(7) "Generic name" means the chemical or established name of a drug product or drug ingredient published in the latest edition of an official compendium recognized by the board.

(8) "Interchangeable biological product" means a biological product that the federal food and drug administration has:

(a) licensed; and

(b) (i) determined meets the standards for interchangeability pursuant to 42 U.S.C. 262(k)(4); or

(ii) determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal food and drug administration's approved drug products with therapeutic equivalence evaluations.

~~(7)~~(9) "Person" has the ~~same~~ meaning ~~as~~ provided in 37-7-101.

~~(8)~~(10) "Prescriber" means a medical practitioner, as defined in 37-2-101, licensed under the professional laws of the state to administer and prescribe medicine and drugs.

~~(9)~~(11) "Present compendium standard" means the official standard for drug excipients and drug products listed in the latest revision of an official compendium recognized by the board.

~~(10)~~(12) "Product selection" means to dispense without the prescriber's express authorization a different drug product in place of the drug product prescribed.

~~(11)~~(13) "Therapeutically equivalent" means those chemical equivalents which, when administered in the same dosage regimen, will provide essentially the same therapeutic effect as measured by the control of a symptom or a disease and/or toxicity."

Section 2. Section 37-7-504, MCA, is amended to read:

"37-7-504. General prohibition of drug product substitution. No person may substitute a drug product different from the one ordered or deviate in any manner from the requirements of an order or prescription, except as provided in this part."

Section 3. Section 37-7-505, MCA, is amended to read:

"37-7-505. Product selection permitted -- limitation. (1) Except as limited by subsection (2) and unless instructed otherwise by the purchaser~~.~~:

(a) ~~the~~ a pharmacist who receives a prescription for a specific drug product by brand or proprietary name may select a less expensive drug product with the same generic name, strength, quantity, dose, and dosage form as the prescribed drug that is, in the pharmacist's professional opinion, therapeutically equivalent, bioequivalent, and bioavailable~~.~~; and

(b) a pharmacist who receives a prescription for a specific biological product may select a less expensive interchangeable biological product.

(2) If, in the professional opinion of the prescriber, it is medically necessary that an equivalent drug product or interchangeable biological product not be selected, the prescriber may so indicate by certifying that the specific brand-name drug product prescribed or the specific brand-name biological product prescribed is

medically necessary for that particular patient. In the case of a prescription transmitted orally, the prescriber must expressly indicate to the pharmacist that the specific brand-name drug product prescribed or the specific biological product prescribed is medically necessary.

(3) (a) Within 5 business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate the specific product provided to the patient, including the name of the product and the manufacturer, to the prescriber through any of the following electric records systems:

(i) an interoperable electronic medical records system;

(ii) an electronic prescribing technology;

(iii) a pharmacy benefit management system; or

(iv) a pharmacy record.

(b) Communication through an electronic records system as described in subsection (3)(a) is presumed to provide notice to the prescriber.

(c) If the pharmacist is unable to communicate pursuant to an electronic records system as provided in subsection (3)(a), the pharmacist shall communicate to the prescriber which biological product was dispensed to the patient using facsimile, telephone, electronic transmission, or other prevailing means.

(d) Communication is not required under this subsection (3) when:

(i) there is no federal food and drug administration approved interchangeable biological product for the product prescribed; or

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

(4) The pharmacist shall maintain a record of the biological product dispensed for at least 2 years.

~~(5) The board shall maintain a link on its website to the current list of all biological products that the federal food and drug administration has determined to be interchangeable biological products.~~"

- END -