HOUSE BILL No. 4812

August 18, 2015, Introduced by Reps. Bizon, Maturen, Muxlow, Canfield, Cox, Santana, Jenkins, Poleski, Inman, Victory, Crawford, Heise, LaVoy, Darany, Singh, Vaupel, Farrington, Glardon, Hughes, Kosowski and Tedder and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled

"Public health code,"

by amending sections 17702, 17704, and 17755 (MCL 333.17702, 333.17704, and 333.17755), sections 17702 and 17704 as amended by 2014 PA 280.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 17702. (1) "Agent" means an individual designated by a prescriber to act on behalf of or at the discretion of that prescriber as provided in section 17744.

(2) "BIOLOGICAL DRUG PRODUCT" MEANS A BIOLOGICAL PRODUCT AS DEFINED IN 42 USC 262.

(3) ~~(2)~~ "Brand name" means the registered trademark name given to a drug product by its manufacturer.

(4) ~~(3)~~ Except as otherwise provided in subsection ~~(4),~~ **(5),** "compounding" means the preparation, mixing, assembling, packaging,

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and labeling of a drug or device by a pharmacist under the following circumstances:

(a) Upon the receipt of a prescription for a specific patient.

(b) Upon the receipt of a medical or dental order from a prescriber or agent for use in the treatment of patients within the course of the prescriber's professional practice.

(c) In anticipation of the receipt of a prescription or medical or dental order based on routine, regularly observed prescription or medical or dental order patterns.

(d) For the purpose of or incidental to research, teaching, or chemical analysis and not for the purpose of sale or dispensing.

(5) ~~(4)~~ "Compounding" does not include any of the following:

(a) Except as provided in section 17748c, the compounding of a drug product that is essentially a copy of a commercially available product.

(b) The reconstitution, mixing, or other similar act that is performed pursuant to the directions contained in approved labeling provided by the manufacturer of a commercially available product.

(c) The compounding of allergenic extracts or biologic products.

(6) ~~(5)~~ "Compounding pharmacy" means a pharmacy that is licensed under this part and is authorized to offer compounding services under sections 17748, 17748a, and 17748b.

(7) ~~(6)~~ "Current selling price" means the retail price for a prescription drug that is available for sale from a pharmacy.

Sec. 17704. (1) "Federal act" means the federal food, drug, and cosmetic act, 21 USC 301 to 399f.

(2) "Food and ~~drug administration"~~ **DRUG ADMINISTRATION"** or "FDA" means the United States ~~food and drug administration.~~**FOOD AND DRUG ADMINISTRATION.**

(3) "Generic name" means the established or official name of a drug or drug product.

(4) "Harmful drug" means a drug intended for use by human beings that is harmful because of its toxicity, habit-forming nature, or other potential adverse effect; the method of its use; or the collateral measures necessary to its safe and effective use and that is designated as harmful by a rule promulgated under this part.

(5) "INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT" MEANS EITHER OF THE FOLLOWING:

(A) A BIOLOGICAL DRUG PRODUCT THAT IS LICENSED BY THE FDA AND DETERMINED TO BE INTERCHANGEABLE WITH THE PRESCRIBED DRUG PRODUCT PURSUANT TO 42 USC 262(K)(4).

(B) A BIOLOGICAL DRUG PRODUCT THAT IS APPROVED BY THE FDA PURSUANT TO AN APPLICATION FILED UNDER 21 USC 355(B)(2) AND THAT THE FDA HAS DETERMINED TO BE THERAPEUTICALLY EQUIVALENT TO THE PRESCRIBED DRUG PRODUCT.

(6) ~~(5)~~ "Internship" means an educational program of professional and practical experience for an intern.

Sec. 17755. (1) ~~When~~ **EXCEPT AS PROVIDED IN SUBSECTION (3), WHEN** a pharmacist receives a prescription for a brand name drug product **OR BIOLOGICAL DRUG PRODUCT**, the pharmacist may, or when a purchaser requests a lower cost generically equivalent drug product **OR INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT**, the pharmacist shall

dispense a lower cost but not higher cost generically equivalent drug product **OR INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT** if available in the pharmacy. ~~, except as provided in subsection (3).~~ If a drug **OR BIOLOGICAL DRUG PRODUCT** is dispensed ~~which~~ **THAT** is not the prescribed brand, the purchaser shall be notified and the prescription label shall indicate both the name of the brand prescribed and the name of the brand dispensed and designate each respectively. ~~If~~ **EXCEPT AS OTHERWISE PROVIDED IN SECTION 17756, IF** the dispensed drug **OR BIOLOGICAL DRUG PRODUCT** does not have a brand name, the prescription label shall indicate the generic name of the drug **OR BIOLOGICAL DRUG PRODUCT** dispensed. ~~, except as otherwise provided in section 17756.~~

(2) If a pharmacist dispenses a generically equivalent drug product **OR INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT**, the pharmacist shall pass on the savings in cost to the purchaser or to the third party payment source if the prescription purchase is covered by a third party pay contract. The savings in cost is the difference between the wholesale cost to the pharmacist of the 2 drug products.

(3) The pharmacist shall not dispense a generically equivalent drug product **OR INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT** under subsection (1) if any of the following ~~applies:~~**APPLY:**

(a) The prescriber, in the case of a prescription in writing signed by the prescriber, writes in his or her own handwriting "dispense as written" or "d.a.w." on the prescription.

(b) The prescriber, having preprinted on his or her prescription blanks the statement "another brand of a generically

equivalent product, identical in dosage, form, and content of active ingredients, may be dispensed unless initialed d.a.w.", writes in his or her own handwriting ~~,—~~the initials "d.a.w." in a space, box, or square adjacent to the statement.

(c) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates **THAT** the prescription is to be dispensed as communicated.

(4) A pharmacist may not dispense a drug product with a total charge that exceeds the total charge of the drug product originally prescribed, unless agreed to by the purchaser.

(5) EXCEPT AS PROVIDED IN SUBSECTION (6), WITHIN 5 BUSINESS DAYS AFTER DISPENSING A BIOLOGICAL DRUG PRODUCT, THE PHARMACIST WHO DISPENSED THE BIOLOGICAL DRUG PRODUCT, A PHARMACY TECHNICIAN, OR A PHARMACIST INTERN SHALL COMMUNICATE TO THE PRESCRIBER THE SPECIFIC BIOLOGICAL DRUG PRODUCT DISPENSED, INCLUDING, BUT NOT LIMITED TO, THE NAME OF THE BIOLOGICAL DRUG PRODUCT AND THE MANUFACTURER OF THE BIOLOGICAL DRUG PRODUCT. THE COMMUNICATION REQUIRED UNDER THIS SUBSECTION SHALL BE MADE AS FOLLOWS:

(A) BY MAKING AN ENTRY IN AN INTEROPERABLE ELECTRONIC MEDICAL RECORDS SYSTEM, THROUGH THE USE OF ELECTRONIC PRESCRIBING TECHNOLOGY, OR THROUGH THE USE OF A PHARMACY RECORD, THAT IS ELECTRONICALLY ACCESSIBLE BY THE PRESCRIBER.

(B) IF THE METHODS DESCRIBED IN SUBDIVISION (A) ARE NOT AVAILABLE, THEN BY FACSIMILE, TELEPHONE, ELECTRONIC TRANSMISSION, OR OTHER PREVAILING MEANS.

(6) SUBSECTION (5) DOES NOT APPLY IF EITHER OF THE FOLLOWING OCCURS:

(A) THERE IS NO INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT FOR THE DRUG PRODUCT PRESCRIBED.

(B) THE PRESCRIPTION WAS REFILLED WITH THE SAME DRUG PRODUCT THAT WAS DISPENSED ON THE PRIOR FILLING OF THE PRESCRIPTION.

(7) THE BOARD SHALL MAINTAIN A LINK ON ITS WEBSITE TO THE CURRENT LIST OF ALL BIOLOGICAL DRUG PRODUCTS THAT THE FDA HAS DETERMINED TO BE INTERCHANGEABLE BIOLOGICAL DRUG PRODUCTS.

Enacting section 1. This amendatory act takes effect 90 days after the date it is enacted into law.