SUBSTITUTE FOR

HOUSE BILL NO. 4472

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), section 17702 as amended by 2016 PA 528 and section 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) "Automated device" means a mechanical system that performs an operation or activity, other than compounding or administration, relating to the storage, packaging, dispensing, or delivery of a drug and that collects, controls, and maintains transaction

information.

(3) "BIOLOGICAL DRUG PRODUCT" MEANS A BIOLOGICAL PRODUCT AS THAT TERM IS DEFINED IN 42 USC 262.

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

(5) ~~(4)~~ Except as otherwise provided in subsection ~~(5),~~ **(6),** "compounding" means the preparation, mixing, assembling, packaging, 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.

(6) ~~(5)~~ "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.

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

(8) ~~(7)~~ "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.~~**399H.**

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

(A) A BIOLOGICAL DRUG PRODUCT THAT IS LICENSED BY THE FDA AND THAT THE FDA HAS DETERMINED MEETS THE STANDARDS FOR INTERCHANGEABILITY UNDER 42 USC 262(K)(4).

(B) UNTIL MARCH 23, 2021, A BIOLOGICAL DRUG PRODUCT THAT THE FDA HAS DETERMINED TO BE THERAPEUTICALLY EQUIVALENT AS SET FORTH IN "APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS", AN FDA PUBLICATION THAT IS COMMONLY REFERRED TO AS THE "ORANGE

BOOK".

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

Sec. 17755. (1) ~~When~~ **EXCEPT AS PROVIDED IN SUBSECTION (2), 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~~ **MUST** be notified and the prescription label ~~shall~~ **MUST** 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~~ **MUST** indicate the generic name of the drug dispensed ~~, except as otherwise provided in section 17756.~~**OR THE PROPRIETARY NAME OF THE BIOLOGICAL DRUG PRODUCT DISPENSED.**

(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 OTHERWISE PROVIDED IN SUBSECTION (6), WITHIN 5 DAYS AFTER DISPENSING AN INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT, THE DISPENSING PHARMACIST OR HIS OR HER DESIGNEE SHALL COMMUNICATE TO THE PRESCRIBER THE SPECIFIC INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT PROVIDED TO THE PATIENT, INCLUDING THE NAME OF THE INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT AND ITS MANUFACTURER. THE COMMUNICATION REQUIRED UNDER THIS SUBSECTION MUST BE MADE AS FOLLOWS:

(A) BY MAKING AN ENTRY THAT IS ELECTRONICALLY ACCESSIBLE TO THE PRESCRIBER THROUGH AN INTEROPERABLE ELECTRONIC MEDICAL RECORDS SYSTEM, AN ELECTRONIC PRESCRIBING TECHNOLOGY, A PHARMACY BENEFIT MANAGEMENT SYSTEM, OR A PHARMACY RECORD. AN ENTRY MADE AS DESCRIBED IN THIS SUBDIVISION IS PRESUMED TO PROVIDE NOTICE TO 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 FDA-LICENSED INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT FOR THE PRODUCT PRESCRIBED.

(B) A REFILL AUTHORIZATION DOES NOT CHANGE THE PRODUCT THAT WAS DISPENSED ON THE PRIOR FILLING OF THE PRESCRIPTION.

(7) THE BOARD SHALL MAINTAIN A LINK ON ITS WEBSITE TO THE CURRENT PURPLE BOOK.

(8) BEGINNING JUNE 1, 2018 AND ANNUALLY THEREAFTER, THE DEPARTMENT SHALL SUBMIT A REPORT ON ALL OF THE FOLLOWING TO THE HOUSE AND SENATE STANDING COMMITTEES ON HEALTH POLICY, THE SPEAKER OF THE HOUSE OF REPRESENTATIVES, AND THE SENATE MAJORITY LEADER:

(A) A LIST OF EACH BIOLOGICAL DRUG PRODUCT THAT THE FDA HAD PREVIOUSLY DETERMINED TO BE THERAPEUTICALLY EQUIVALENT AS SET FORTH IN THE ORANGE BOOK THAT IS NOW INCLUDED IN THE PURPLE BOOK.

(B) THE ANTICIPATED DATE THAT EVERY BIOLOGICAL DRUG PRODUCT THAT THE FDA HAS DETERMINED TO BE THERAPEUTICALLY EQUIVALENT AS SET FORTH IN THE ORANGE BOOK WILL BE INCLUDED IN THE PURPLE BOOK.

(9) AS USED IN THIS SECTION:

(A) "ORANGE BOOK" MEANS "APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS," AN FDA PUBLICATION THAT IS COMMONLY REFERRED TO AS THE "ORANGE BOOK".

(B) "PURPLE BOOK" MEANS "LISTS OF BIOLOGICAL PRODUCTS WITH REFERENCE PRODUCT EXCLUSIVITY AND BIOSIMILARITY OR INTERCHANGEABILITY EVALUATIONS", AN FDA PUBLICATION THAT IS COMMONLY REFERRED TO AS THE "PURPLE BOOK".

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