HOUSE BILL No. 4437

April 14, 2015, Introduced by Rep. Yonker and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled

"Public health code,"

by amending sections 17702, 17704, 17709, and 17755 (MCL 333.17702, 333.17704, 333.17709, and 333.17755), sections 17702, 17704, and 17709 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) "BIOSIMILAR" MEANS THAT TERM AS DEFINED IN 42 USC 262.

(4) "BIOSIMILAR DRUG PRODUCT" MEANS A BIOLOGICAL DRUG PRODUCT THAT THE FDA HAS DETERMINED TO BE BIOSIMILAR TO A REFERENCE

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PRODUCT.

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

(6) ~~(3)~~ Except as otherwise provided in subsection ~~(4),~~ **(7),** "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.

(7) ~~(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.

(8) ~~(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.

(9) ~~(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" MEANS THAT TERM AS DEFINED IN 42 USC 262.

(6) "INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT" MEANS A BIOLOGICAL DRUG PRODUCT THAT HAS MET THE SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY UNDER 42 USC 262 AND IS THEREFORE DETERMINED TO BE INTERCHANGEABLE WITH A REFERENCE PRODUCT BY THE FDA.

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

Sec. 17709. **(1) "REFERENCE PRODUCT" MEANS THAT TERM AS DEFINED IN 42 USC 262.**

(2) ~~(1)~~ "Sign" means to affix one's signature manually to a document or to use an electronic signature when transmitting a prescription electronically.

(3) ~~(2)~~ "Sterile pharmaceutical" means a dosage form of a drug that is essentially free from living microbes and chemical or physical contamination to the point at which it poses no present risk to the patient, in accordance with USP standards. As used in this subsection, "dosage form" includes, but is not limited to, parenteral, injectable, and ophthalmic dosage forms.

(4) ~~(3)~~ "Substitute" means to dispense, without the prescriber's authorization, a different drug in place of the drug prescribed.

(5) ~~(4)~~ "USP standards" means the pharmacopeial standards for drug substances, dosage forms, and compounded preparations based on designated levels of risk as published in the official compendium.

(6) ~~(5)~~ "Wholesale distributor" means a person, other than a manufacturer, who supplies, distributes, sells, offers for sale, barters, or otherwise disposes of, to other persons for resale, compounding, or dispensing, a drug or device salable on prescription only that the distributor has not prepared, produced, derived, propagated, compounded, processed, packaged, or repackaged, or otherwise changed the container or the labeling of the drug or device.

Sec. 17755. (1) ~~When~~ **EXCEPT AS OTHERWISE PROVIDED IN THIS SECTION,** a pharmacist **WHO** receives a prescription for a brand name drug product ~~, the pharmacist may, or when a purchaser requests a lower cost generically equivalent drug product, the pharmacist~~

~~shall~~ **OR A BIOLOGICAL DRUG PRODUCT MAY** dispense a lower cost ~~but not higher cost~~ generically equivalent drug product **OR LOWER COST INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT** if available in the pharmacy. ~~, except as provided in subsection (3). If~~ **EXCEPT AS OTHERWISE PROVIDED IN THIS SECTION, UPON THE REQUEST OF THE PURCHASER, A PHARMACIST WHO RECEIVES A PRESCRIPTION FOR A BRAND NAME DRUG PRODUCT OR A BIOLOGICAL DRUG PRODUCT SHALL DISPENSE A LOWER COST GENERICALLY EQUIVALENT DRUG PRODUCT OR LOWER COST INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT IF AVAILABLE IN THE PHARMACY. THE PHARMACIST SHALL NOTIFY THE PURCHASER IF** a drug is dispensed ~~which~~ **THAT** is not the prescribed brand ~~, the purchaser shall be notified and the prescription label~~ **NAME DRUG PRODUCT OR THE PRESCRIBED BIOLOGICAL DRUG PRODUCT. EXCEPT AS OTHERWISE PROVIDED IN SECTION 17756, THE PHARMACIST** shall indicate both the ~~name of the~~ brand **NAME OF THE DRUG PRODUCT** prescribed **OR THE BIOLOGICAL DRUG PRODUCT PRESCRIBED** and the **GENERIC** name **OR INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT NAME** of the ~~brand~~ **DRUG PRODUCT** dispensed and designate each respectively **ON THE PRESCRIPTION LABEL**. ~~If~~ **EXCEPT AS OTHERWISE PROVIDED IN SECTION 17756, IF** the dispensed drug does not have a brand name, the ~~prescription label~~ **PHARMACIST** shall indicate the generic name **OR INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT NAME** of the drug **PRODUCT** dispensed ~~, except as otherwise provided in section 17756.~~**ON THE PRESCRIPTION LABEL.**

(2) If a pharmacist dispenses a generically equivalent drug product **OR AN INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT UNDER SUBSECTION (1)**, 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) IF A PHARMACIST DISPENSES AN INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT UNDER SUBSECTION (1), THE PHARMACIST SHALL INDICATE THE INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT NAME AND THE FULL NAME OF THE MANUFACTURER, IF AVAILABLE, OF THE INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT DISPENSED ON THE FILE COPY OF THE PRESCRIPTION.

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

(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 **DRUG** product **OR AN INTERCHANGEABLE BIOLOGICAL DRUG 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~~ **1** in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as communicated.

(5) ~~(4)~~ A pharmacist ~~may~~ **SHALL** 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.

(6) EXCEPT AS OTHERWISE PROVIDED IN SUBSECTION (1), A PHARMACIST MUST NOTIFY THE PRESCRIBER BEFORE DISPENSING A BIOSIMILAR DRUG PRODUCT IN PLACE OF A BIOLOGICAL DRUG PRODUCT.

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