HOUSE BILL No. 5643

May 16, 2012, Introduced by Reps. Lori, Haines, Tyler, Graves, Wayne Schmidt and Hobbs and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled

"Public health code,"

by amending section 17755 (MCL 333.17755) and by adding section 17755a.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 17755. (1) ~~When~~ **IF** a pharmacist receives a prescription for a brand name drug product, the pharmacist may, or ~~when~~ **IF** a purchaser requests a lower cost generically equivalent drug product, the pharmacist shall dispense a lower cost but not higher cost generically equivalent drug product if available in the pharmacy, except as provided in subsection (3) **AND SECTION 17755A**. If a drug is dispensed ~~which~~ **THAT** is not the prescribed brand, the **PHARMACIST SHALL NOTIFY THE** purchaser ~~shall be notified~~ and **INDICATE ON** the prescription label ~~shall indicate~~ both the name of the brand prescribed and the name of the brand dispensed and

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designate each respectively. If the dispensed drug does not have a brand name, the **PHARMACIST SHALL INDICATE ON THE** prescription label ~~shall indicate~~ the generic name of the drug dispensed, except as otherwise provided in section 17756.

(2) If a pharmacist dispenses a generically equivalent 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~~ **A** pharmacist shall not dispense a generically equivalent 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 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 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.

SEC. 17755A. (1) THE MICHIGAN BOARD OF PHARMACY SHALL CREATE A LIST OF THE OPIOID ANALGESIC DRUGS FOR WHICH IT HAS RECEIVED EVIDENCE FROM THE DRUG MANUFACTURER OR DISTRIBUTOR THAT THE DRUG MEETS ALL OF THE FOLLOWING:

(A) IT INCORPORATES A TAMPER-RESISTANCE TECHNOLOGY.

(B) IT HAS BEEN APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION PURSUANT TO AN APPLICATION THAT INCLUDED AT LEAST 1 HUMAN TAMPERING OR ABUSE POTENTIAL STUDY OR A LABORATORY STUDY COMPARING THE TAMPER-RESISTANCE OR ABUSE-RESISTANCE PROPERTIES OF THE DRUG TO 1 OR MORE OPIOID ANALGESIC DRUGS THAT HAVE BEEN APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION AND THAT SERVE AS A POSITIVE CONTROL.

(2) THE MICHIGAN BOARD OF PHARMACY MAY NOT EXCLUDE AN OPIOID ANALGESIC DRUG FROM THE LIST DESCRIBED IN SUBSECTION (1) BECAUSE THE DRUG DOES NOT BEAR A LABELING CLAIM WITH RESPECT TO REDUCTION OF TAMPERING, ABUSE, OR ABUSE POTENTIAL AT THE TIME THE DRUG IS INCLUDED IN THE LIST. THE LIST SHALL ALSO INCLUDE A DETERMINATION BY THE BOARD AS TO WHICH OPIOID ANALGESIC DRUGS INCORPORATING TAMPER-RESISTANCE TECHNOLOGIES INCLUDED ON THE LIST PROVIDE SUBSTANTIALLY SIMILAR TAMPER-RESISTANCE PROPERTIES, BASED SOLELY ON STUDIES SUBMITTED TO THE UNITED STATES FOOD AND DRUG ADMINISTRATION BY THE DRUG MANUFACTURER AND DESCRIBED IN SUBSECTION (1)(B)

(3) A PHARMACIST SHALL NOT INTERCHANGE OR SUBSTITUTE AN OPIOID ANALGESIC DRUG, BRAND OR GENERIC, OTHERWISE ELIGIBLE FOR INTERCHANGE OR SUBSTITUTION UNDER SECTION 17755 FOR AN OPIOID ANALGESIC DRUG INCORPORATING A TAMPER-RESISTANCE TECHNOLOGY WITHOUT

DOING 1 OF THE FOLLOWING:

(A) VERIFYING THAT THE MICHIGAN BOARD OF PHARMACY HAS DETERMINED UNDER SUBSECTION (2) THAT THE OPIOID ANALGESIC DRUG PROVIDES TAMPER-RESISTANCE PROPERTIES SUBSTANTIALLY SIMILAR TO THE PRESCRIBED OPIOID ANALGESIC DRUG INCORPORATING A TAMPER-RESISTANCE TECHNOLOGY.

(B) OBTAINING WRITTEN, SIGNED CONSENT FROM THE PRESCRIBER FOR THE INTERCHANGE OR SUBSTITUTION.

(4) AS USED IN THIS SECTION:

(A) "INTERCHANGE OR SUBSTITUTION OF AN OPIOID ANALGESIC DRUG" MEANS THE SUBSTITUTION OF ANY OPIOID ANALGESIC DRUG, BRAND OR GENERIC, FOR A PRESCRIBED OPIOID ANALGESIC DRUG INCORPORATING A TAMPER-RESISTANCE TECHNOLOGY, WHETHER OR NOT THE SUBSTITUTED DRUG IS RATED AS PHARMACEUTICALLY AND THERAPEUTICALLY EQUIVALENT BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR MICHIGAN BOARD OF PHARMACY OR WHETHER THE OPIOID ANALGESIC DRUG WITH TAMPER-RESISTANCE TECHNOLOGY BEARS A LABELING CLAIM WITH RESPECT TO REDUCTION OF TAMPERING, ABUSE, OR ABUSE POTENTIAL.

(B) "OPIOID ANALGESIC DRUG" MEANS A DRUG IN THE OPIOID DRUG CLASS PRESCRIBED TO TREAT MODERATE TO SEVERE PAIN OR OTHER CONDITIONS, INCLUDING OPIOID DEPENDENCE, WHETHER IN IMMEDIATE RELEASE OR EXTENDED RELEASE FORM AND WHETHER OR NOT COMBINED WITH OTHER DRUG SUBSTANCES TO FORM A SINGLE TABLET OR OTHER DOSAGE FORM.

(C) "OPIOID ANALGESIC DRUG INCORPORATING A TAMPER-RESISTANCE TECHNOLOGY" MEANS AN OPIOID ANALGESIC DRUG LISTED AS SUCH BY THE MICHIGAN BOARD OF PHARMACY UNDER SUBSECTION (1).