HOUSE BILL No. 4662

May 19, 2011, Introduced by Reps. Lori and Meadows and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled

"Public health code,"

by amending sections 7340, 17708, and 17766d (MCL 333.7340, 333.17708, and 333.17766d), section 7340 as added by 2006 PA 261, section 17708 as amended by 2009 PA 150, and section 17766d as added by 2004 PA 329; and to repeal acts and parts of acts.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 7340. (1) A person shall not sell, distribute, deliver, or otherwise furnish a product that contains any compound, mixture, or preparation containing any detectable quantity of ephedrine or pseudoephedrine, a salt or optical isomer of ephedrine or pseudoephedrine, or a salt of an optical isomer of ephedrine or pseudoephedrine to an individual if the sale is transacted through use of the mail, internet, telephone, or other electronic means.

(2) This section does not apply to any of the following:

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~~(a) A pediatric product primarily intended for administration to children under 12 years of age according to label instructions.~~

~~(b) A product containing pseudoephedrine that is in a liquid form if pseudoephedrine is not the only active ingredient.~~

(A) ~~(c)~~ A product that the state board of pharmacy, upon application of the manufacturer or certification by the United States drug enforcement administration as inconvertible, exempts from this section because the product has been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine.

(B) ~~(d)~~ A person who dispenses a product described in subsection (1) pursuant to a prescription.

(C) ~~(e)~~ A person who, in the course of his or her business, sells or distributes products described in subsection (1) to ~~either of the following:~~

~~(*i*) A~~ **A** person licensed by this state to manufacture, deliver, dispense, or possess with intent to manufacture or deliver a controlled substance, prescription drug, or other drug.

~~(*ii*) A person who orders those products described in subsection (1) for retail sale pursuant to a license issued under the general sales tax act, 1933 PA 167, MCL 205.51 to 205.78.~~

(D) ~~(f)~~ A manufacturer or distributor who donates product samples to a nonprofit charitable organization that has tax-exempt status ~~pursuant to~~ **UNDER** section 501(c)(3) of the internal revenue code of 1986, a licensed practitioner, or a governmental entity.

(3) A person who violates this section is guilty of a felony punishable by imprisonment for not more than 4 years or a fine of

not more than $5,000.00, or both.

Sec. 17708. (1) "Preceptor" means a pharmacist approved by the board to direct the training of an intern in an approved pharmacy.

(2) "Prescriber" means a licensed dentist, a licensed doctor of medicine, a licensed doctor of osteopathic medicine and surgery, a licensed doctor of podiatric medicine and surgery, a licensed optometrist certified under part 174 to administer and prescribe therapeutic pharmaceutical agents, a licensed veterinarian, or another licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed doctor of medicine or licensed doctor of osteopathic medicine and surgery.

(3) "Prescription" means an order for a drug or device written and signed or transmitted by facsimile, electronic transmission, or other means of communication by a prescriber to be filled, compounded, or dispensed. Prescribing is limited to a prescriber. An order transmitted in other than written form shall be electronically recorded, printed, or written and immediately dated by the pharmacist, and that record constitutes the original prescription. In a health facility or agency licensed under article 17 or other medical institution, an order for a drug or device in the patient's chart constitutes for the purposes of this definition the original prescription. Subject to section 17751(2), prescription includes, but is not limited to, an order for a drug, not including a controlled substance as defined in section 7104 except under circumstances described in section 17763(e), written and signed or transmitted by facsimile, electronic transmission, or

other means of communication by a physician prescriber licensed to practice in a state other than Michigan.

(4) "Prescription drug" means 1 or more of the following:

(a) A drug dispensed pursuant to a prescription.

(b) A drug bearing the federal legend "CAUTION: federal law prohibits dispensing without prescription" or "Rx only".

(c) A drug designated by the board as a drug that may only be dispensed pursuant to a prescription.

(D) EPHEDRINE, A SALT OF EPHEDRINE, AN OPTICAL ISOMER OF EPHEDRINE, A SALT OF AN OPTICAL ISOMER OF EPHEDRINE, OR A COMPOUND, MIXTURE, OR PREPARATION CONTAINING EPHEDRINE, A SALT OF EPHEDRINE, AN OPTICAL ISOMER OF EPHEDRINE, OR A SALT OF AN OPTICAL ISOMER OF EPHEDRINE.

Sec. 17766d. (1) ~~Notwithstanding section 17766(f), a~~ **A** pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail may accept for the purpose of resale or redispensing a prescription drug that has been dispensed and has left the control of the pharmacist if the prescription drug is being returned by a state correctional facility or a county jail that has a licensed physician's assistant, a registered professional nurse, or a licensed practical nurse, who is responsible for the security, handling, and administration of prescription drugs within that state correctional facility or county jail and if all of the following are met:

(a) The pharmacist is satisfied that the conditions under which the prescription drug has been delivered, stored, and handled

before and during its return were such as to prevent damage, deterioration, or contamination that would adversely affect the identity, strength, quality, purity, stability, integrity, or effectiveness of the prescription drug.

(b) The pharmacist is satisfied that the prescription drug did not leave the control of the registered professional nurse or licensed practical nurse responsible for the security, handling, and administration of that prescription drug and that the prescription drug did not come into the physical possession of the individual for whom it was prescribed.

(c) The pharmacist is satisfied that the labeling and packaging of the prescription drug are accurate, have not been altered, defaced, or tampered with, and include the identity, strength, expiration date, and lot number of the prescription drug.

(d) The prescription drug was dispensed in a unit dose package or unit of issue package.

(2) A pharmacy operated by the department of corrections or under contract with the department of corrections or a county jail shall not accept for return prescription drugs as provided under this section until the pharmacist in charge develops a written set of protocols for accepting, returning to stock, repackaging, labeling, and redispensing prescription drugs. The written protocols shall be maintained on the premises and shall be readily accessible to each pharmacist on duty. The written protocols shall include, at a minimum, each of the following:

(a) Methods to ensure that damage, deterioration, or contamination has not occurred during the delivery, handling,

storage, and return of the prescription drugs which would adversely affect the identity, strength, quality, purity, stability, integrity, or effectiveness of those prescription drugs or otherwise render those drugs unfit for distribution.

(b) Methods for accepting, returning to stock, repackaging, labeling, and redispensing the prescription drugs returned under this section.

(c) A uniform system of recording and tracking prescription drugs that are returned to stock, repackaged, labeled, and redistributed under this section.

(3) If the integrity of a prescription drug and its package is maintained, a prescription drug returned under this section shall be returned to stock and redistributed as follows:

(a) A prescription drug that was originally dispensed in the manufacturer's unit dose package or unit of issue package and is returned in that same package may be returned to stock, repackaged, and redispensed as needed.

(b) A prescription drug that is repackaged into a unit dose package or a unit of issue package by the pharmacy, dispensed, and returned to that pharmacy in that unit dose package or unit of issue package may be returned to stock, but it shall not be repackaged. A unit dose package or unit of issue package prepared by the pharmacist and returned to stock shall only be redispensed in that same unit dose package or unit of issue package and shall only be redispensed once. A pharmacist shall not add unit dose package drugs to a partially used unit of issue package.

(4) This section does not apply to any of the following:

(a) A controlled substance.

(b) A prescription drug that is dispensed as part of a customized patient medication package.

(c) A prescription drug that is not dispensed as a unit dose package or a unit of issue package.

(d) A prescription drug that is not properly labeled with the identity, strength, lot number, and expiration date.

(e) A prescription drug that is dispensed in a medical institution and returned to stock for redistribution in accordance with R 338.486 of the Michigan administrative code.

(5) As used in this section:

(a) "County jail" means a facility operated by a county for the physical detention and correction of persons charged with, or convicted of, criminal offenses or ordinance violations or persons found guilty of civil or criminal contempt.

(b) "Customized patient medication package" means a package that is prepared by a pharmacist for a specific patient that contains 2 or more prescribed solid oral dosage forms.

(c) "Repackage" means a process by which the pharmacy prepares a unit dose package, unit of issue package, or customized patient medication package for immediate dispensing pursuant to a current prescription.

(d) "State correctional facility" means a facility or institution that houses a prisoner population under the jurisdiction of the department of corrections.

(e) "Unit dose package" means a package that contains a single dose drug with the name, strength, control number, and expiration

date of that drug on the label.

(f) "Unit of issue package" means a package that provides multiple doses of the same drug, but each drug is individually separated and includes the name, lot number, and expiration date.

Enacting section 1. Sections 17766c, 17766e, and 17766f of the public health code, 1978 PA 368, MCL 333.17766c, 333.17766e, and 333.17766f, are repealed.

Enacting section 2. This amendatory act takes effect January 1, 2012.