HOUSE BILL No. 6286

September 29, 2004, Introduced by Reps. Bieda, Gleason, Lipsey, Wojno and Gieleghem and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled

"Public health code,"

by amending sections 17766 and 21413 (MCL 333.17766 and 333.21413), section 17766 as amended by 1990 PA 30 and section 21413 as amended by 1996 PA 267, and by adding section 17766d.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 17766. Except as provided in section ~~17766a~~ **17766d**, a person who does any of the following is guilty of a misdemeanor:

(a) Obtains or attempts to obtain a prescription drug by giving a false name to a pharmacist or other authorized seller, prescriber, or dispenser.

(b) Obtains or attempts to obtain a prescription drug by falsely representing that he or she is a lawful prescriber, dispenser, or licensee, or acting on behalf of a lawful

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prescriber, dispenser, or licensee.

(c) Falsely makes, utters, publishes, passes, alters, or forges a prescription.

(d) Knowingly possesses a false, forged, or altered prescription.

(e) Knowingly attempts to obtain, obtains, or possesses a drug by means of a prescription for other than a legitimate therapeutic purpose, or as a result of a false, forged, or altered prescription.

(f) Possesses or controls for the purpose of resale, or sells, offers to sell, dispenses, or gives away, a drug, pharmaceutical preparation, or chemical that has been dispensed on prescription and has left the control of a pharmacist. ~~, or~~

(g) Possesses or controls for the purpose of resale, or sells, offers to sell, dispenses, or gives away, a drug, pharmaceutical preparation, or chemical that has been damaged by heat, smoke, fire, water, or other cause and is unfit for human or animal use.

(h) ~~(g)~~ Prepares or permits the preparation of a prescription drug, except as delegated by a pharmacist.

(i) ~~(h)~~ Sells a drug in bulk or in an open package at auction, unless the sale has been approved in accordance with rules of the board.

Sec. 17766d. (1) Notwithstanding section 17766(f), a pharmacy 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 hospice residence licensed under article 17 that has a registered professional nurse or a licensed practical nurse who is responsible for the security, handling, and administration of prescription drugs within that hospice facility 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 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) "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.

(b) "Hospice residence" means that term as defined under section 21401.

(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) "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.

(e) "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.

Sec. 21413. (1) The owner, operator, and governing body of a hospice or hospice residence licensed under this article:

(a) Are responsible for all phases of the operation of the hospice or hospice residence and for the quality of care and services rendered by the hospice or hospice residence.

(b) Shall cooperate with the department in the enforcement of this part, and require that the physicians and other personnel working in the hospice or hospice residence and for whom a license or registration is required be currently licensed or registered.

(c) Shall not discriminate because of race, religion, color, national origin, or sex, in the operation of the hospice or hospice residence including employment, patient admission and care, and room assignment.

(2) As a condition of licensure as a hospice residence, an applicant shall have been licensed under this article as a hospice and in compliance with the standards set forth in 42 ~~C.F.R.~~ **CFR** part 418 for not less than the 2 years immediately preceding the date of application for licensure. A hospice residence licensed under this article may provide both home care

and inpatient care at the same location. A hospice residence providing inpatient care shall comply with the standards in 42 ~~C.F.R.~~ **CFR** 418.100.

(3) In addition to the requirements of subsections (1) and (2) and section 21415, the owner, operator, and governing body of a hospice residence that is licensed under this article and that provides care only at the home care level shall do all of the following:

(a) Provide 24-hour nursing services for each patient in accordance with the patient's hospice care plan as required under 42 ~~C.F.R.~~ **CFR** part 418.

(b) Have an approved plan for infection control that includes making provisions for isolating each patient with an infectious disease.

(c) Obtain fire safety approval pursuant to section 20156.

(d) Equip each patient room with a device approved by the department for calling the staff member on duty.

(e) Design and equip areas within the hospice residence for the comfort and privacy of each patient and his or her family members.

(f) Permit patients to receive visitors at any hour, including young children.

(g) Provide individualized meal service plans in accordance with 42 ~~C.F.R.~~ **CFR** 418.100(j).

(h) Provide appropriate methods and procedures for the storage, dispensing, ~~and~~ administering**, and disposal or return** of drugs and biologicals pursuant to 42 ~~C.F.R.~~ **CFR** 418.100(k).