

HOUSE BILL No. 5547

October 27, 2009, Introduced by Reps. Liss, Roy Schmidt, Ball and Byrum and referred to the Committee on Ethics and Elections.

A bill to amend 1978 PA 368, entitled "Public health code," by amending sections 17703, 17704, 17706, and 17707 (MCL 333.17703, 333.17704, 333.17706, and 333.17707), section 17703 as amended by 2006 PA 672, section 17706 as amended by 1986 PA 304, and section 17707 as amended by 1990 PA 333, and by adding section 17746a.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 Sec. 17703. (1) "Device" means an instrument, apparatus, or
2 contrivance, including its components, parts, and accessories,
3 intended for use in the diagnosis, cure, mitigation, treatment, or
4 prevention of disease in human beings or other animals, or to
5 affect the structure or function of the body of human beings or

1 other animals.

2 (2) "Dispense" means to issue 1 or more doses of a drug for
3 subsequent administration to, or use by, a patient.

4 (3) "Dispensing prescriber" means a prescriber, other than a
5 veterinarian, who dispenses prescription drugs.

6 (4) "Drug" means any of the following:

7 (a) A substance recognized or for which the standards or
8 specifications are prescribed in the official compendium.

9 (b) A substance intended for use in the diagnosis, cure,
10 mitigation, treatment, or prevention of disease in human beings or
11 other animals.

12 (c) A substance, other than food, intended to affect the
13 structure or a function of the body of human beings or other
14 animals.

15 (d) A substance intended for use as a component of a substance
16 specified in subdivision (a), (b), or (c), but not including a
17 device or its components, parts, or accessories.

18 (5) "Electronic signature" means an electronic sound, symbol,
19 or process attached to or logically associated with a record and
20 executed or adopted by a person with the intent to sign the record.

21 (6) "Electronically transmitted prescription" means the
22 communication of an original prescription or refill authorization
23 by electronic means including computer to computer, computer to
24 facsimile machine, or electronic mail transmission that contains
25 the same information it contained when the prescriber or authorized
26 agent transmitted the prescription. Electronically transmitted
27 prescription does not include a prescription or refill

1 authorization transmitted by telephone or facsimile machine.

2 (7) "EMERGENCY DRUGS" ARE THOSE DRUGS THAT ARE REQUIRED TO
3 MEET THE IMMEDIATE THERAPEUTIC NEED OF A RESIDENT OF A MEDICAL
4 INSTITUTION AND THAT ARE TO BE ADMINISTERED BY AUTHORIZED PERSONNEL
5 TO THE RESIDENT BEFORE THE INTERPRETATION AND REVIEW BY A
6 PHARMACIST WHEN WAITING FOR INTERPRETATION AND REVIEW WOULD CAUSE A
7 MEDICALLY UNACCEPTABLE DELAY.

8 Sec. 17704. (1) "Federal act" means the federal food, drug,
9 and cosmetic act, ~~of 1938,~~ 21 U.S.C. USC 301 to ~~392-399A~~.

10 (2) "Generic name" means the established or official name of a
11 drug or drug product.

12 (3) "Harmful drug" means a drug intended for use by human
13 beings ~~which~~ THAT is harmful because of its toxicity, habit-forming
14 nature, or other potential adverse effect, the method of its use,
15 or the collateral measures necessary to its safe and effective use,
16 and ~~which~~ THAT is designated as harmful by the board according to
17 rule.

18 (4) "INSTITUTIONAL PHARMACY" MEANS A PHARMACY LICENSED UNDER
19 THIS PART THAT IS LOCATED IN THIS STATE; THAT DISPENSES, COMPOUNDS,
20 AND DISTRIBUTES DRUGS, DEVICES, AND OTHER MATERIALS; AND THAT
21 ENGAGES IN THE PRACTICE OF PHARMACY FOR A MEDICAL INSTITUTION.

22 (5) ~~(4)~~ "Internship" means an educational program of
23 professional and practical experience for an intern.

24 Sec. 17706. (1) "Manufacturer" means a person who prepares,
25 produces, derives, propagates, compounds, processes, packages, or
26 repackages a drug or device salable on prescription only, or
27 otherwise changes the container or the labeling of a drug or device

1 salable on prescription only, and who supplies, distributes, sells,
2 offers for sale, barter, or otherwise disposes of that drug or
3 device and any other drug or device salable on prescription only,
4 to another person for resale, compounding, or dispensing.

5 (2) "MEDICAL INSTITUTION" MEANS A FEDERALLY- OR STATE-LICENSED
6 ORGANIZATION OR FACILITY THE PRIMARY PURPOSE OF WHICH IS TO PROVIDE
7 A PHYSICAL ENVIRONMENT AT WHICH ON-SITE MEDICAL CARE IS PROVIDED TO
8 INDIVIDUALS AND A PERMANENT MEDICAL RECORD DOCUMENTING THE
9 PROVISION OF MEDICAL CARE, INCLUDING MEDICATIONS ORDERED AND
10 ADMINISTERED, TO THAT INDIVIDUAL IS MAINTAINED. MEDICAL INSTITUTION
11 INCLUDES, BUT IS NOT LIMITED TO, A HOSPITAL, CONVALESCENT HOME,
12 HOME FOR THE AGED, NURSING HOME, SKILLED NURSING FACILITY, COUNTY
13 MEDICAL CARE FACILITY, EXTENDED CARE FACILITY, ADULT FOSTER CARE
14 FACILITY, ASSISTED LIVING FACILITY, MENTAL HEALTH FACILITY,
15 PSYCHIATRIC CENTER, DEVELOPMENTAL DISABILITY CENTER, AND ANY OTHER
16 HEALTH FACILITY OR AGENCY THAT IS LICENSED UNDER ARTICLE 17 AND
17 THAT DIRECTLY OR INDIRECTLY PROVIDES OR INCLUDES PHARMACY SERVICES
18 TO RESIDENTS.

19 (3) "MEDICATION DRUG KITS" ARE THOSE DRUGS THAT MAY BE
20 REQUIRED TO MEET THE THERAPEUTIC NEEDS OF A RESIDENT OF A MEDICAL
21 INSTITUTION WHEN A PHARMACIST IS NOT IN PERSONAL CHARGE OF THE
22 INSTITUTIONAL PHARMACY.

23 (4) "MEDICATION ORDER" MEANS A LAWFUL ORDER ENTERED ON THE
24 PERMANENT MEDICAL RECORD OF A RESIDENT OF A MEDICAL INSTITUTION BY
25 A PRESCRIBER AND IS CONSIDERED A PRESCRIPTION DRUG ORDER. IF
26 WRITTEN, THE MEDICATION ORDER SHALL INCLUDE THE SIGNATURE OF THE
27 PRESCRIBER OR PERSONNEL AUTHORIZED BY THE MEDICAL INSTITUTION OR,

1 **IF ELECTRONICALLY TRANSMITTED, THE APPROPRIATE ELECTRONIC**
2 **SIGNATURE.**

3 (5) ~~(2)~~—"Official compendium" means the United States
4 pharmacopoeia and national formulary, homeopathic pharmacopoeia of
5 the United States, or a supplement thereof existing on July 1,
6 1983.

7 Sec. 17707. (1) "Personal charge" means the immediate physical
8 presence of a pharmacist or dispensing prescriber.

9 (2) "Pharmacist" means an individual licensed under this
10 article to engage in the practice of pharmacy.

11 (3) "Pharmacist intern" or "intern" means an individual who
12 satisfactorily completes the requirements set forth in rules
13 promulgated by the board and is licensed by the board for the
14 purpose of obtaining instruction in the practice of pharmacy from a
15 preceptor approved by the board.

16 (4) "Pharmacy" means a building or part of a building in which
17 the practice of pharmacy is conducted.

18 (5) "Practice of pharmacy" means a health service, the
19 clinical application of which includes the encouragement of safety
20 and efficacy in the prescribing, dispensing, administering, and use
21 of drugs and related articles for the prevention of illness, and
22 the maintenance and management of health. **PRACTICE OF PHARMACY**

23 **INCLUDES THE DIRECT OR INDIRECT PROVISION OF PATIENT CARE SERVICES**
24 **ASSOCIATED WITH THE PRACTICE OF PHARMACY TO MEDICAL INSTITUTIONS.**

25 Professional functions associated with the practice of pharmacy
26 include:

27 (a) The interpretation and evaluation of the prescription.

1 (b) Drug product selection.

2 (c) The compounding, dispensing, safe storage, and
3 distribution of drugs and devices.

4 (d) The maintenance of legally required records.

5 (e) Advising the prescriber and the patient as required as to
6 contents, therapeutic action, utilization, and possible adverse
7 reactions or interactions of drugs.

8 SEC. 17746A. (1) A PHARMACIST IN CHARGE OF AN INSTITUTIONAL
9 PHARMACY SHALL MAKE ARRANGEMENT IN ADVANCE FOR THE PERIOD OF TIME
10 DURING WHICH A PHARMACIST IS NOT IN PERSONAL CHARGE OF THE
11 INSTITUTIONAL PHARMACY. A PHARMACIST SHALL BE ON CALL AND AVAILABLE
12 TO THE MEDICAL STAFF AND OTHER AUTHORIZED PERSONNEL OF THE MEDICAL
13 INSTITUTION FOR THE PERIOD OF TIME DURING WHICH A PHARMACIST IS NOT
14 IN PERSONAL CHARGE OF THE INSTITUTIONAL PHARMACY. A PHARMACIST IN
15 CHARGE SHALL INCLUDE IN THE ARRANGEMENT UNDER THIS SUBSECTION A
16 METHOD TO PROVIDE DRUGS TO THE MEDICAL STAFF AND OTHER AUTHORIZED
17 PERSONNEL OF A MEDICAL INSTITUTION BY USE OF EMERGENCY DRUGS OR
18 MEDICATION DRUG KITS, OR BOTH. A PHARMACIST IN CHARGE MAY INCLUDE
19 IN EMERGENCY DRUGS OR MEDICATION DRUG KITS THOSE DRUGS THAT MAY BE
20 REQUIRED TO MEET THE IMMEDIATE THERAPEUTIC NEEDS OF A RESIDENT OF
21 THE MEDICAL INSTITUTION AND THAT ARE NOT AVAILABLE FROM ANY OTHER
22 AUTHORIZED SOURCE IN SUFFICIENT TIME TO PREVENT RISK OF HARM TO THE
23 RESIDENT BECAUSE OF DELAY RESULTING FROM OBTAINING THE DRUGS FROM
24 OTHER SOURCES.

25 (2) WHEN A PHARMACIST IS NOT IN PERSONAL CHARGE OF THE
26 INSTITUTIONAL PHARMACY, EMERGENCY DRUGS AND MEDICATION DRUG KITS
27 SHALL BE STORED IN SECURED AREAS OF THE MEDICAL INSTITUTION TO

1 PREVENT UNAUTHORIZED ACCESS AND IN AREAS DESIGNED TO ENSURE A
2 PROPER ENVIRONMENT FOR PRESERVATION OF THE DRUGS. THE PHARMACIST IN
3 CHARGE, IN CONJUNCTION WITH THE APPROPRIATE COMMITTEE OF THE
4 MEDICAL INSTITUTION, SHALL DO ALL OF THE FOLLOWING:

5 (A) DEVELOP INVENTORY LISTINGS OF THE DRUGS CONTAINED IN THE
6 EMERGENCY DRUGS AND MEDICATION DRUG KITS, INCLUDING NAME, STRENGTH,
7 QUANTITY, AND EXPIRATION DATE OF THE CONTENTS.

8 (B) DETERMINE WHO IS AUTHORIZED ACCESS TO THE EMERGENCY DRUGS
9 AND MEDICATION DRUGS KITS AND UNDER WHAT CIRCUMSTANCES.

10 (C) ENSURE THAT ALL OF THE EMERGENCY DRUGS AND MEDICATION
11 DRUGS KITS ARE PROPERLY LABELED.

12 (D) ENSURE THAT ONLY A LIMITED NUMBER OF DRUGS IN UNIT DOSE OR
13 UNIT-OF-USE PACKAGING ARE AVAILABLE IN AMOUNTS SUFFICIENT FOR
14 IMMEDIATE THERAPEUTIC REQUIREMENTS OF RESIDENTS.

15 (E) TO PREVENT DIVERSION OF THE EMERGENCY DRUGS AND MEDICATION
16 DRUG KITS, INSTITUTE CONTROLS AND RECORD-KEEPING PROCEDURES TO
17 ADEQUATELY ACCOUNT FOR THE DRUGS AND TO ENSURE THAT ALL OF THE
18 FOLLOWING OCCUR:

19 (i) THAT EMERGENCY DRUGS AND MEDICATION DRUG KITS ARE REMOVED
20 FROM THE SECURE AREA ONLY PURSUANT TO A VALID MEDICATION ORDER.

21 (ii) THAT ONLY AUTHORIZED INDIVIDUALS ARE ABLE TO ACCESS THE
22 EMERGENCY DRUGS AND MEDICATION DRUG KITS AND THAT DOCUMENTATION OF
23 THAT ACCESS IS MAINTAINED.

24 (iii) THAT DOCUMENTATION OF PROOF-OF-USE BY RESIDENTS OR RETURN
25 OF THE UNUSED EMERGENCY DRUGS AND MEDICATION DRUG KITS TO THE
26 SECURE AREA IS PROVIDED.

27 (iv) THAT ANY OTHER RECORD-KEEPING REQUIREMENT DETERMINED

1 NECESSARY UNDER THIS SECTION IS MET.

2 (F) PROVIDE PROCEDURES FOR THE INSPECTION OF THE INVENTORY OF
3 THE EMERGENCY DRUGS AND MEDICATION DRUG KITS TO ASSURE PROPER
4 UTILIZATION AND REPLACEMENT OF THE DRUG SUPPLY.

5 (G) UPON NOTIFICATION THAT AN EMERGENCY DRUG OR MEDICATION
6 DRUG KIT IS USED, RESTOCK EMERGENCY DRUGS AND MEDICATION DRUG KITS
7 WITHIN A REASONABLE TIME SO AS TO PREVENT RISK OF HARM TO
8 RESIDENTS.

9 (H) ESTABLISH ANY OTHER WRITTEN POLICIES AND PROCEDURES
10 NECESSARY TO IMPLEMENT THE REQUIREMENTS OF THIS SECTION.