## SUBSTITUTE FOR HOUSE BILL NO. 5877

A bill to amend 1978 PA 368, entitled "Public health code," by amending sections 17702, 17703, and 17707 (MCL 333.17702,

333.17703, and 333.17707), section 17702 as amended by 2014 PA 280 and sections 17703 and 17707 as amended by 2014 PA 285, and by adding section 17760.

## THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

- 1 Sec. 17702. (1) "Agent" means an individual designated by a
- 2 prescriber to act on behalf of or at the discretion of that
- 3 prescriber as provided in section 17744.
- 4 (2) "AUTOMATED DEVICE" MEANS A MECHANICAL SYSTEM THAT PERFORMS
- 5 AN OPERATION OR ACTIVITY, OTHER THAN COMPOUNDING OR ADMINISTRATION,
- 6 RELATING TO THE STORAGE, PACKAGING, DISPENSING, OR DELIVERY OF A
- 7 DRUG AND THAT COLLECTS, CONTROLS, AND MAINTAINS TRANSACTION

## 1 INFORMATION.

- 2 (3) (2) "Brand name" means the registered trademark name given
- 3 to a drug product by its manufacturer.
- 4 (4)  $\frac{(3)}{(3)}$  Except as otherwise provided in subsection  $\frac{(4)}{(3)}$ , (5),
- 5 "compounding" means the preparation, mixing, assembling, packaging,
- 6 and labeling of a drug or device by a pharmacist under the
- 7 following circumstances:
- 8 (a) Upon the receipt of a prescription for a specific patient.
- 9 (b) Upon the receipt of a medical or dental order from a
- 10 prescriber or agent for use in the treatment of patients within the
- 11 course of the prescriber's professional practice.
- 12 (c) In anticipation of the receipt of a prescription or
- 13 medical or dental order based on routine, regularly observed
- 14 prescription or medical or dental order patterns.
- 15 (d) For the purpose of or incidental to research, teaching, or
- 16 chemical analysis and not for the purpose of sale or dispensing.
- 17 (5) (4) "Compounding" does not include any of the following:
- 18 (a) Except as provided in section 17748c, the compounding of a
- 19 drug product that is essentially a copy of a commercially available
- 20 product.
- 21 (b) The reconstitution, mixing, or other similar act that is
- 22 performed pursuant to the directions contained in approved labeling
- 23 provided by the manufacturer of a commercially available product.
- 24 (c) The compounding of allergenic extracts or biologic
- 25 products.
- **26 (6)** <del>(5)</del> "Compounding pharmacy" means a pharmacy that is
- 27 licensed under this part and is authorized to offer compounding

- 1 services under sections 17748, 17748a, and 17748b.
- 2 (7) (6)—"Current selling price" means the retail price for a
- 3 prescription drug that is available for sale from a pharmacy.
- 4 Sec. 17703. (1) "DELIVER" OR "DELIVERY" MEANS THE ACTUAL,
- 5 CONSTRUCTIVE, OR ATTEMPTED TRANSFER OF A DRUG OR DEVICE FROM 1
- 6 PERSON TO ANOTHER.
- 7 (2) (1) "Device" means an instrument, apparatus, or
- 8 contrivance, including its components, parts, and accessories,
- 9 intended for use in the diagnosis, cure, mitigation, treatment, or
- 10 prevention of disease in human beings or other animals, or to
- 11 affect the structure or function of the body of human beings or
- 12 other animals.
- 13 (3) (2) "Dispense" means to issue 1 or more doses of a drug
- 14 for subsequent administration to, or use by, a patient. THE
- 15 PREPARATION, COMPOUNDING, PACKAGING, OR LABELING OF A DRUG PURSUANT
- 16 TO A PRESCRIPTION OR OTHER AUTHORIZATION ISSUED BY A PRESCRIBER.
- 17 (4) (3)—"Dispensing prescriber" means a prescriber, other than
- 18 a veterinarian, who dispenses prescription drugs.
- 19 (5) EXCEPT AS OTHERWISE PROVIDED IN SECTION 17780,
- 20 "DISTRIBUTE" OR "DISTRIBUTION" MEANS TO SELL, OFFER FOR SALE,
- 21 DELIVER, OFFER TO DELIVER, BROKER, GIVE AWAY, OR TRANSFER A DRUG,
- 22 WHETHER BY PASSAGE OF TITLE OR PHYSICAL MOVEMENT. THE TERM DOES NOT
- 23 INCLUDE ANY OF THE FOLLOWING:
- 24 (A) DISPENSING OR ADMINISTERING A DRUG.
- 25 (B) THE DELIVERY OF A DRUG, OR OFFERING TO DELIVER A DRUG, BY
- 26 A COMMON CARRIER IN THE USUAL COURSE OF BUSINESS AS A COMMON
- 27 CARRIER.

## 1 (C) THE DELIVERY OF A DRUG VIA AN AUTOMATED DEVICE UNDER

- 2 SECTION 17760.
- **3 (6)** <del>(4)</del> "Drug" means any of the following:
- 4 (a) A substance recognized or for which the standards or
- 5 specifications are prescribed in the official compendium.
- 6 (b) A substance intended for use in the diagnosis, cure,
- 7 mitigation, treatment, or prevention of disease in human beings or
- 8 other animals.
- 9 (c) A substance, other than food, intended to affect the
- 10 structure or a function of the body of human beings or other
- 11 animals.
- 12 (d) A substance intended for use as a component of a substance
- 13 specified in subdivision (a), (b), or (c), but not including a
- 14 device or its components, parts, or accessories.
- 15 (7) (5) "Electronic signature" means an electronic sound,
- 16 symbol, or process attached to or logically associated with a
- 17 record and executed or adopted by a person with the intent to sign
- 18 the record.
- 19 (8) (6)—"Electronically transmitted prescription" means the
- 20 communication of an original prescription or refill authorization
- 21 by electronic means including computer to computer, computer to
- 22 facsimile machine, or electronic mail transmission that contains
- 23 the same information it contained when the prescriber or his or her
- 24 agent transmitted the prescription. Electronically transmitted
- 25 prescription does not include a prescription or refill
- 26 authorization transmitted by telephone or facsimile machine.
- Sec. 17707. (1) "Personal charge" means the immediate physical

- 1 presence of a pharmacist or dispensing prescriber.
- 2 (2) "Pharmacist" means an individual licensed under this
- 3 article to engage in the practice of pharmacy.
- 4 (3) "Pharmacist in charge" or "PIC" means the pharmacist who
- 5 is designated by a pharmacy, manufacturer, or wholesale distributor
- 6 as its pharmacist in charge under section 17748(2).
- 7 (4) "Pharmacist intern" or "intern" means an individual who
- 8 satisfactorily completes the requirements set forth in rules
- 9 promulgated by the department in consultation with the board and is
- 10 licensed by the board for the purpose of obtaining instruction in
- 11 the practice of pharmacy from a preceptor approved by the board.
- 12 (5) "Pharmacy" means a building FACILITY or part of a building
- 13 in which the practice of pharmacy is conducted. FACILITY THAT IS
- 14 LICENSED UNDER THIS PART TO DISPENSE PRESCRIPTION DRUGS OR PREPARE
- 15 PRESCRIPTION DRUGS FOR DELIVERY OR DISTRIBUTION. PHARMACY DOES NOT
- 16 INCLUDE THE OFFICE OF A DISPENSING PRESCRIBER OR AN AUTOMATED
- 17 DEVICE. For the purpose of a duty placed on a pharmacy under this
- 18 part, "pharmacy" means the person to which the pharmacy license is
- 19 issued, unless otherwise specifically provided.
- 20 (6) "Pharmacy technician" means an individual who is required
- 21 to hold a health profession subfield license under this part to
- 22 serve as a pharmacy technician.
- 23 (7) "Practice of pharmacy" means a health service, the
- 24 clinical application of which includes the encouragement of safety
- 25 and efficacy in the prescribing, dispensing, administering, and use
- 26 of drugs and related articles for the prevention of illness, and
- 27 the maintenance and management of health. Practice of pharmacy

- 1 includes the direct or indirect provision of professional functions
- 2 and services associated with the practice of pharmacy. Professional
- 3 functions associated with the practice of pharmacy include:
- 4 (a) The interpretation and evaluation of the prescription.
- 5 (b) Drug product selection.
- 6 (c) The compounding, dispensing, safe storage, and
- 7 distribution of drugs and devices.
- 8 (d) The maintenance of legally required records.
- **9** (e) Advising the prescriber and the patient as required as to
- 10 contents, therapeutic action, utilization, and possible adverse
- 11 reactions or interactions of drugs.
- 12 SEC. 17760. (1) A PHARMACY THAT IS OWNED AND OPERATED BY A
- 13 HOSPITAL LICENSED UNDER ARTICLE 17 MAY OPERATE AN AUTOMATED DEVICE
- 14 AT A LOCATION THAT IS AFFILIATED WITH THE HOSPITAL BUT THAT IS NOT
- 15 LOCATED AT THE SAME PHYSICAL ADDRESS AS THE PHARMACY. A PHARMACY
- 16 THAT OPERATES AN AUTOMATED DEVICE UNDER THIS SECTION SHALL NOTIFY
- 17 THE DEPARTMENT OF THE AUTOMATED DEVICE'S LOCATION.
- 18 (2) AN AUTOMATED DEVICE THAT IS OPERATED UNDER THIS SECTION
- 19 MUST BE UNDER THE CONTROL AND SUPERVISION OF THE PHARMACIST IN
- 20 CHARGE FOR THE PHARMACY DESCRIBED IN SUBSECTION (1). THE PHARMACIST
- 21 IN CHARGE FOR THE PHARMACY DESCRIBED IN SUBSECTION (1) MAY, IN
- 22 ACCORDANCE WITH THE REQUIREMENTS FOR DELEGATION AND SUPERVISION IN
- 23 THIS ARTICLE, DELEGATE THE STOCKING OF THE AUTOMATED DEVICE, THE
- 24 REMOVAL OF MEDICATION FROM THE AUTOMATED DEVICE, THE MAINTENANCE OF
- 25 THE AUTOMATED DEVICE, AND OTHER TASKS RELATED TO THE OPERATION OF
- 26 THE AUTOMATED DEVICE, BUT HE OR SHE IS NOT REQUIRED TO BE
- 27 IMMEDIATELY PHYSICALLY PRESENT TO SUPERVISE A DELEGATED TASK. THE

- 1 OPERATION OF THE AUTOMATED DEVICE IS LIMITED TO LICENSED HEALTH
- 2 PROFESSIONALS.
- Enacting section 1. This amendatory act takes effect 90 days 3
- 4 after the date it is enacted into law.