HB-5407, As Passed House, October 1, 2014HB-5407, As Passed Senate, September 24, 2014

SENATE SUBSTITUTE FOR

HOUSE BILL NO. 5407

A bill to amend 1978 PA 368, entitled "Public health code,"

by amending sections 1106, 17745, 17751, 17754, and 17757 (MCL 333.1106, 333.17745, 333.17751, 333.17754, and 333.17757), section 1106 as amended by 2000 PA 58, sections 17745, 17751, and 17757 as amended by 2013 PA 186, and section 17754 as amended by 2013 PA 268, and by adding sections 7421 and 17744b.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 1106. (1) "OPIOID ANTAGONIST" MEANS NALOXONE
 HYDROCHLORIDE OR ANY OTHER SIMILARLY ACTING AND EQUALLY SAFE DRUG
 APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION FOR THE
 TREATMENT OF DRUG OVERDOSE.

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(2) "OPIOID-RELATED OVERDOSE" MEANS A CONDITION, INCLUDING,

BUT NOT LIMITED TO, EXTREME PHYSICAL ILLNESS, DECREASED LEVEL OF
 CONSCIOUSNESS, RESPIRATORY DEPRESSION, COMA, OR DEATH, THAT RESULTS
 FROM THE CONSUMPTION OR USE OF AN OPIOID OR ANOTHER SUBSTANCE WITH
 WHICH AN OPIOID WAS COMBINED OR THAT A LAYPERSON WOULD REASONABLY
 BELIEVE TO BE AN OPIOID-RELATED OVERDOSE THAT REQUIRES MEDICAL
 ASSISTANCE.

7 (3) (1) "Parentage registry" means the department's compilation of data concerning children's parentage, which data the 8 9 department receives from any source, including, but not limited to, a copy of an order of filiation from the circuit court or an 10 11 acknowledgment of paternity or parentage under this act, under 12 section 2114 of the estates and protected individuals code, 1998 PA 13 386, MCL 700.2114, or under the acknowledgment of parentage act, 14 1996 PA 305, MCL 722.1001 to 722.1013.

15 (4) (2) "Person" means an individual, partnership, 16 cooperative, association, private corporation, personal 17 representative, receiver, trustee, assignee, or other legal entity. 18 Person does not include a governmental entity unless specifically 19 provided.

20 SEC. 7421. BY FEBRUARY 1 EACH YEAR, THE DEPARTMENT OF COMMUNITY HEALTH SHALL ASCERTAIN, DOCUMENT, AND PUBLISH A REPORT ON 21 THE NUMBER, TRENDS, PATTERNS, AND RISK FACTORS RELATED TO OPIOID-22 RELATED OVERDOSE FATALITIES THAT OCCURRED IN THIS STATE IN THE 23 PRECEDING CALENDAR YEAR. THE DEPARTMENT SHALL INCLUDE IN THE REPORT 24 25 INFORMATION ON INTERVENTIONS THAT WOULD BE EFFECTIVE IN REDUCING 26 THE RATE OF FATAL OR NONFATAL OPIOID-RELATED OVERDOSES IN THIS 27 STATE.

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SEC. 17744B. (1) NOTWITHSTANDING ANY PROVISION OF THIS ACT TO
 THE CONTRARY, A PRESCRIBER MAY ISSUE A PRESCRIPTION FOR AND A
 DISPENSING PRESCRIBER OR PHARMACIST MAY DISPENSE AN OPIOID
 ANTAGONIST TO ANY OF THE FOLLOWING:

5 (A) AN INDIVIDUAL PATIENT AT RISK OF EXPERIENCING AN OPIOID6 RELATED OVERDOSE.

7 (B) A FAMILY MEMBER, FRIEND, OR OTHER INDIVIDUAL IN A POSITION
8 TO ASSIST AN INDIVIDUAL AT RISK OF EXPERIENCING AN OPIOID-RELATED
9 OVERDOSE.

10 (C) A PERSON OTHER THAN AN INDIVIDUAL THAT MEETS ALL OF THE 11 FOLLOWING REQUIREMENTS:

12 (i) ACTS AT THE DIRECTION OF THE PRESCRIBER OR DISPENSING
13 PRESCRIBER.

14 (*ii*) UPON RECEIPT OF AN OPIOID ANTAGONIST, STORES THE OPIOID
15 ANTAGONIST IN COMPLIANCE WITH THIS PART.

16 (*iii*) DISPENSES OR ADMINISTERS AN OPIOID ANTAGONIST UNDER A
17 VALID PRESCRIPTION ISSUED TO AN INDIVIDUAL OR A PATIENT.

18 (*iv*) PERFORMS THE REQUIREMENTS UNDER THIS SUBSECTION WITHOUT
 19 CHARGE OR COMPENSATION.

(2) WHEN ISSUING A PRESCRIPTION FOR OR DISPENSING AN OPIOID
ANTAGONIST AS AUTHORIZED UNDER THIS SECTION TO A PERSON OTHER THAN
A PATIENT, THE PRESCRIBER, DISPENSING PRESCRIBER, OR PHARMACIST, AS
APPROPRIATE, SHALL INSERT THE NAME OF THE PERSON AS THE NAME OF THE
PATIENT.

(3) NOTWITHSTANDING ANY PROVISION OF THIS ACT TO THE CONTRARY,
A PERSON THAT IS ACTING IN GOOD FAITH AND WITH REASONABLE CARE MAY
POSSESS AND DISPENSE AN OPIOID ANTAGONIST.

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(4) A PRESCRIBER WHO ISSUES A PRESCRIPTION FOR OR A DISPENSING
 PRESCRIBER OR PHARMACIST WHO DISPENSES AN OPIOID ANTAGONIST AS
 AUTHORIZED UNDER THIS SECTION IS NOT LIABLE IN A CIVIL ACTION FOR A
 PROPERLY STORED AND DISPENSED OPIOID ANTAGONIST THAT WAS A
 PROXIMATE CAUSE OF INJURY OR DEATH TO AN INDIVIDUAL DUE TO THE
 ADMINISTRATION OF OR FAILURE TO ADMINISTER THE OPIOID ANTAGONIST.

7 Sec. 17745. (1) Except as otherwise provided in this subsection, a prescriber who wishes to dispense prescription drugs 8 9 shall obtain from the board a drug control license for each 10 location in which the storage and dispensing of prescription drugs 11 occur. A drug control license is not necessary if the dispensing occurs in the emergency department, emergency room, or trauma 12 center of a hospital licensed under article 17 or if the dispensing 13 14 involves only the issuance of complimentary starter dose drugs.

15 (2) Except as otherwise provided in section 17744a OR 17744B,
16 a dispensing prescriber shall dispense prescription drugs only to
17 his or her own patients.

18 (3) A dispensing prescriber shall include in a patient's chart 19 or clinical record a complete record, including prescription drug 20 names, dosages, and quantities, of all prescription drugs dispensed 21 directly by the dispensing prescriber or indirectly under his or 22 her delegatory authority. If prescription drugs are dispensed under 23 the prescriber's delegatory authority, the delegatee who dispenses 24 the prescription drugs shall initial the patient's chart, clinical 25 record, or log of prescription drugs dispensed. In a patient's 26 chart or clinical record, a dispensing prescriber shall distinguish 27 between prescription drugs dispensed to the patient, prescription

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1 drugs prescribed for the patient, and prescription drugs dispensed 2 or prescribed as authorized under section 17744a OR 17744B. A 3 dispensing prescriber shall retain information required under this 4 subsection for not less than 5 years after the information is 5 entered in the patient's chart or clinical record.

6 (4) A dispensing prescriber shall store prescription drugs
7 under conditions that will maintain their stability, integrity, and
8 effectiveness and will assure that the prescription drugs are free
9 of contamination, deterioration, and adulteration.

10 (5) A dispensing prescriber shall store prescription drugs in 11 a substantially constructed, securely lockable cabinet. Access to 12 the cabinet shall be limited to individuals authorized to dispense 13 prescription drugs in compliance with this part and article 7.

14 (6) Unless otherwise requested by a patient, a dispensing
15 prescriber shall dispense a prescription drug in a safety closure
16 container that complies with the poison prevention packaging act of
17 1970, 15 USC 1471 to 1477.

18 (7) A dispensing prescriber shall dispense a drug in a
19 container that bears a label containing all of the following
20 information:

(a) The name and address of the location from which theprescription drug is dispensed.

23 (b) Except as otherwise authorized under section 17744a OR
24 17744B, the patient's name and record number.

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(c) The date the prescription drug was dispensed.

26 (d) The prescriber's name or, if dispensed under the27 prescriber's delegatory authority, the name of the delegatee.

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(e) The directions for use.

2 (f) The name and strength of the prescription drug.

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(g) The quantity dispensed.

4 (h) The expiration date of the prescription drug or the5 statement required under section 17756.

(8) A dispensing prescriber who dispenses a complimentary 6 starter dose drug to a patient shall give the patient at least all 7 of the following information, either by dispensing the 8 9 complimentary starter dose drug to the patient in a container that bears a label containing the information or by giving the patient a 10 11 written document that may include, but is not limited to, a 12 preprinted insert that comes with the complimentary starter dose drug, that contains all of the following information: 13

14 (a) The name and strength of the complimentary starter dose15 drug.

16 (b) Directions for the patient's use of the complimentary17 starter dose drug.

18 (c) The expiration date of the complimentary starter dose drug19 or the statement required under section 17756.

20 (9) The information required under subsection (8) is in
21 addition to, and does not supersede or modify, other state or
22 federal law regulating the labeling of prescription drugs.

(10) In addition to meeting the requirements of this part, a
dispensing prescriber who dispenses controlled substances shall
comply with section 7303a.

26 (11) The board may periodically inspect locations from which27 prescription drugs are dispensed.

(12) The act, task, or function of dispensing prescription 1 2 drugs shall be delegated only as provided in this part and sections 16215, 17048, 17076, 17212, and 17548. 3

4 (13) A supervising physician may delegate in writing to a 5 pharmacist practicing in a hospital pharmacy within a hospital licensed under article 17 the receipt of complimentary starter dose 6 7 drugs other than controlled substances as defined by article 7 or federal law. When the delegated receipt of complimentary starter 8 9 dose drugs occurs, both the pharmacist's name and the supervising physician's name shall be used, recorded, or otherwise indicated in 10 11 connection with each receipt. A pharmacist described in this 12 subsection may dispense a prescription for complimentary starter dose drugs written or transmitted by facsimile, electronic 13 14 transmission, or other means of communication by a prescriber.

(14) As used in this section, "complimentary starter dose" 15 16 means a prescription drug packaged, dispensed, and distributed in 17 accordance with state and federal law that is provided to a 18 dispensing prescriber free of charge by a manufacturer or 19 distributor and dispensed free of charge by the dispensing 20 prescriber to his or her patients.

21 Sec. 17751. (1) A pharmacist shall not dispense a drug 22 requiring a prescription under the federal act or a law of this 23 state except under authority of an original prescription or an 24 equivalent record of an original prescription approved by the 25 board.

26 (2) Subject to subsection (5), a pharmacist may dispense a 27 prescription written and signed; written or created in an

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electronic format, signed, and transmitted by facsimile; or 1 2 transmitted electronically or by other means of communication by a physician prescriber or dentist prescriber in a state other than 3 4 Michigan, but not including a prescription for a controlled substance as defined in section 7104 except under circumstances 5 described in section 17763(e), only if the pharmacist in the 6 exercise of his or her professional judgment determines all of the 7 following: 8

9 (a) Except as otherwise authorized under section 17744a OR
10 17744B, that the prescription was issued pursuant to an existing
11 physician-patient or dentist-patient relationship.

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(b) That the prescription is authentic.

13 (c) That the prescribed drug is appropriate and necessary for14 the treatment of an acute, chronic, or recurrent condition.

(3) A pharmacist or a prescriber shall dispense a prescription
only if the prescription falls within the scope of practice of the
prescriber.

18 (4) A pharmacist shall not knowingly dispense a prescription19 after the death of the prescriber or patient.

(5) A pharmacist shall not dispense a drug or device under a
prescription transmitted by facsimile or created in electronic
format and printed out for use by the patient unless the document
is manually signed by the prescriber. This subsection does not
apply to a prescription that is transmitted by a computer to a
facsimile machine if that prescription complies with section 17754.

26 (6) After consultation with and agreement from the prescriber,27 a pharmacist may add or change a patient's address, dosage form,

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drug strength, drug quantity, directions for use, or issue date 1 2 with regard to a prescription. A pharmacist shall note the details of the consultation and agreement required under this subsection on 3 4 the prescription and shall maintain that documentation with the 5 prescription as required in section 17752. A pharmacist shall not change the patient's name, controlled substance prescribed unless 6 7 authorized to dispense a lower cost generically equivalent drug product under section 17755, or the prescriber's signature with 8 9 regard to a prescription.

10 (7) A prescription that is contained within a patient's chart 11 in a health facility or agency licensed under article 17 or other 12 medical institution and that is transmitted to a pharmacy under 13 section 17744 is the original prescription. If all other 14 requirements of this part are met, a pharmacist shall dispense a drug or device under a prescription described in this subsection. A 15 pharmacist may dispense a drug or device under a prescription 16 17 described in this subsection even if the prescription does not contain the quantity ordered. If a prescription described in this 18 19 subsection does not contain the quantity ordered, the pharmacist 20 shall consult with the prescriber to determine an agreed-upon 21 quantity. The pharmacist shall record the quantity dispensed on the 22 prescription and shall maintain that documentation with the 23 prescription as required in section 17752.

Sec. 17754. (1) Except as otherwise provided under article 7, article 8, and the federal act, a prescription may be transmitted electronically if the prescription is transmitted in compliance with the health insurance portability and accountability act of

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1996, Public Law 104-191, or regulations promulgated under that
 act, 45 CFR parts 160 and 164, by a prescriber or his or her agent
 and the data are not altered or modified in the transmission
 process. The electronically transmitted prescription shall include
 all of the following information:

6 (a) The name, address, and telephone number of the prescriber.
7 (b) Except as otherwise authorized under section 17744a OR
8 17744B, the full name of the patient for whom the prescription is
9 issued.

10 (c) An electronic signature or other identifier that
11 specifically identifies and authenticates the prescriber or his or
12 her agent.

13 (d) The time and date of the transmission.

14 (e) The identity of the pharmacy intended to receive the15 transmission.

16 (f) Any other information required by the federal act or state 17 law.

18 (2) The electronic equipment or system utilized in the 19 transmission and communication of prescriptions shall provide 20 adequate confidentiality safeguards and be maintained to protect 21 patient confidentiality as required under any applicable federal 22 and state law and to ensure against unauthorized access. The 23 electronic transmission of a prescription shall be communicated in 24 a retrievable, recognizable form acceptable to the intended 25 recipient. The electronic form utilized in the transmission of a 26 prescription shall not include "dispense as written" or "d.a.w." as 27 the default setting.

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(3) Before dispensing a prescription that is electronically
 transmitted, the pharmacist shall exercise professional judgment
 regarding the accuracy, validity, and authenticity of the
 transmitted prescription.

5 (4) An electronically transmitted prescription that meets the6 requirements of this section is the original prescription.

7 Sec. 17757. (1) Upon a request made in person or by telephone, a pharmacist engaged in the business of selling drugs at retail 8 shall provide the current selling price of a drug dispensed by that 9 10 pharmacy or comparative current selling prices of generic and brand 11 name drugs dispensed by that pharmacy. The information shall be 12 provided to the person making the request before a drug is 13 dispensed to the person. A person who makes a request for price 14 information under this subsection is not obligated to purchase the drug for which the price or comparative prices are requested. 15

16 (2) A pharmacist engaged in the business of selling drugs at 17 retail shall conspicuously display the notice described in 18 subsection (3) at each counter over which prescription drugs are 19 dispensed.

20 (3) The notice required under subsection (2) shall be in21 substantially the following form:

22 NOTICE TO CONSUMERS
 23 ABOUT PRESCRIPTION DRUGS
 24 Under Michigan law, you have the right to find out the price

of a prescription drug before the pharmacist fills the prescription. You are under no obligation to have the prescription filled here and may use this price information to shop around at

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other pharmacies. You may request price information in person or by
 telephone.

3 Every pharmacy has the current selling prices of both generic4 and brand name drugs dispensed by the pharmacy.

Ask your pharmacist if a lower-cost generic drug is available
to fill your prescription. A generic drug contains the same
medicine as a brand name drug and is a suitable substitute in most
instances.

9 A generic drug may not be dispensed by your pharmacist if your
10 doctor has written "dispense as written" or the initials "d.a.w."
11 on the prescription.

12 If you have questions about the drugs that have been 13 prescribed for you, ask your doctor or pharmacist for more 14 information.

15 To avoid dangerous drug interactions, let your doctor and 16 pharmacist know about any other medications you are taking. This is 17 especially important if you have more than 1 doctor or have 18 prescriptions filled at more than 1 pharmacy.

19 (4) The notice required under subsection (2) shall also
20 contain the address and phone number of the board and the
21 department. The text of the notice shall be in at least 32-point
22 bold type and shall be printed on paper at least 11 inches by 17
23 inches in size. The notice may be printed on multiple pages.

24 (5) A-THE DEPARTMENT SHALL PROVIDE A copy of the notice
25 required under subsection (2) shall be provided to each licensee.
26 by the department. The department shall provide additional copies
27 if needed. A person may duplicate or reproduce the notice if the

duplication or reproduction is a true copy of the notice as
 produced by the department, without any additions or deletions.

3 (6) The pharmacist shall furnish to the purchaser of a
4 prescription drug at the time the drug is delivered to the
5 purchaser a receipt evidencing the transactions, which contains all
6 of the following:

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(a) The brand name of the drug, if applicable.

8 (b) The name of the manufacturer or the supplier of the drug,9 if the drug does not have a brand name.

10 (c) The strength of the drug, if significant.

11 (d) The quantity dispensed, if applicable.

12 (e) The name and address of the pharmacy.

13 (f) The serial number of the prescription.

14 (g) The date the prescription was originally dispensed.

15 (h) The name of the prescriber or, if prescribed under the16 prescriber's delegatory authority, the name of the delegatee.

17 (i) Except as otherwise authorized under section 17744a OR
18 17744B, the name of the patient for whom the drug was prescribed.

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(j) The price for which the drug was sold to the purchaser.

20 (7) The items required under subsection (6)(a), (b), and (c) 21 may be omitted by a pharmacist only if the omission is expressly required by the prescriber. The pharmacist shall retain a copy of 22 23 each receipt for 90 days. The inclusion of the items required under 24 subsection (6) on the prescription container label is a valid 25 receipt to the purchaser. Including the items required under 26 subsection (6) on the written prescription form and retaining the 27 form constitutes retention of a copy of the receipt.

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