SUBSTITUTE FOR HOUSE BILL NO. 6323

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

by amending sections 7405, 17702, 17703, 17708, 17709, 17745, 17751, and 17763 (MCL 333.7405, 333.17702, 333.17703, 333.17708, 333.17709, 333.17745, 333.17751, and 333.17763), section 7405 as amended by 2004 PA 536, section 17702 as amended by 1986 PA 304, section 17703 as amended by 1992 PA 281, sections 17708, 17751, and 17763 as amended by 2005 PA 85, and section 17745 as amended by 1997 PA 186, and by adding section 17754.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

- 1 Sec. 7405. (1) A person:
- 2 (a) Who is licensed by the administrator under this article
- 3 shall not distribute, prescribe, or dispense a controlled substance
- 4 in violation of section 7333.
- 5 (b) Who is a licensee shall not manufacture a controlled

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- 1 substance not authorized by his or her license or distribute,
- 2 prescribe, or dispense a controlled substance not authorized by his
- 3 or her license to another licensee or other authorized person,
- 4 except as authorized by rules promulgated by the administrator.
- 5 (c) Shall not refuse an entry into any premises for an
- 6 inspection authorized by this article.
- 7 (d) Shall not knowingly keep or maintain a store, shop,
- 8 warehouse, dwelling, building, vehicle, boat, aircraft, or other
- 9 structure or place, that is frequented by persons using controlled
- 10 substances in violation of this article for the purpose of using
- 11 controlled substances, or that is used for keeping or selling
- 12 controlled substances in violation of this article.
- (e) Who is a practitioner shall not dispense a prescription
- 14 for a controlled substance written and signed or transmitted by
- 15 FACSIMILE, ELECTRONIC TRANSMISSION, OR OTHER MEANS OF COMMUNICATION
- 16 BY a physician prescriber licensed to practice in a state other
- 17 than Michigan, unless the prescription is issued by a physician
- 18 prescriber who resides adjacent to the land border between this
- 19 state and an adjoining state or resides in Illinois or Minnesota
- 20 and who is authorized under the laws of that state to practice
- 21 medicine or osteopathic medicine and surgery and to prescribe
- 22 controlled substances and whose practice may extend into this
- 23 state, but who does not maintain an office or designate a place to
- 24 meet patients or receive calls in this state.
- 25 (2) A person who violates subsection (1) is subject to the
- 26 penalties prescribed in section 7406.
- 27 Sec. 17702. (1) "AGENT" MEANS AN AUTHORIZED PERSON WHO ACTS ON

1 BEHALF OF OR AT THE DISCRETION OF A PRESCRIBER.

- 2 (2) "Brand name" means the registered trademark name given to
- 3 a drug product by its manufacturer.
- 4 (3) -(2) "Current selling price" means the retail price for a
- 5 prescription drug which is available for sale from a pharmacy.
- 6 Sec. 17703. (1) "Device" means an instrument, apparatus, or
- 7 contrivance, including its components, parts, and accessories,
- 8 intended for use in the diagnosis, cure, mitigation, treatment, or
- 9 prevention of disease in human beings or other animals, or to
- 10 affect the structure or function of the body of human beings or
- 11 other animals.
- 12 (2) "Dispense" means to issue 1 or more doses of a drug for
- 13 subsequent administration to, or use by, a patient.
- 14 (3) "Dispensing prescriber" means a prescriber, other than a
- 15 veterinarian, who dispenses prescription drugs.
- 16 (4) "Drug" means any of the following:
- 17 (a) A substance recognized or for which the standards or
- 18 specifications are prescribed in the official compendium.
- 19 (b) A substance intended for use in the diagnosis, cure,
- 20 mitigation, treatment, or prevention of disease in human beings or
- 21 other animals.
- 22 (c) A substance, other than food, intended to affect the
- 23 structure or a function of the body of human beings or other
- 24 animals.
- 25 (d) A substance intended for use as a component of a substance
- 26 specified in subdivision (a), (b), or (c), but not including a
- 27 device or its components, parts, or accessories.

- 1 (5) "ELECTRONIC SIGNATURE" MEANS AN ELECTRONIC SOUND, SYMBOL,
- 2 OR PROCESS ATTACHED TO OR LOGICALLY ASSOCIATED WITH A RECORD AND
- 3 EXECUTED OR ADOPTED BY A PERSON WITH THE INTENT TO SIGN THE RECORD.
- 4 (6) "ELECTRONICALLY TRANSMITTED PRESCRIPTION" MEANS THE
- 5 COMMUNICATION OF AN ORIGINAL PRESCRIPTION OR REFILL AUTHORIZATION
- 6 BY ELECTRONIC MEANS INCLUDING COMPUTER TO COMPUTER, COMPUTER TO
- 7 FACSIMILE MACHINE, OR ELECTRONIC MAIL TRANSMISSION THAT CONTAINS
- 8 THE SAME INFORMATION IT CONTAINED WHEN THE PRESCRIBER OR AUTHORIZED
- 9 AGENT TRANSMITTED THE PRESCRIPTION. ELECTRONICALLY TRANSMITTED
- 10 PRESCRIPTION DOES NOT INCLUDE A PRESCRIPTION OR REFILL
- 11 AUTHORIZATION TRANSMITTED BY TELEPHONE OR FACSIMILE MACHINE.
- Sec. 17708. (1) "Preceptor" means a pharmacist approved by the
- 13 board to direct the training of an intern in an approved pharmacy.
- 14 (2) "Prescriber" means a licensed dentist, a licensed doctor
- 15 of medicine, a licensed doctor of osteopathic medicine and surgery,
- 16 a licensed doctor of podiatric medicine and surgery, a licensed
- 17 optometrist certified under part 174 to administer and prescribe
- 18 therapeutic pharmaceutical agents, a licensed veterinarian, or
- 19 another licensed health professional acting under the delegation
- 20 and using, recording, or otherwise indicating the name of the
- 21 delegating licensed doctor of medicine or licensed doctor of
- 22 osteopathic medicine and surgery.
- 23 (3) "Prescription" means an order for a drug or device written
- 24 and signed or transmitted by FACSIMILE, ELECTRONIC TRANSMISSION, OR
- 25 other means of communication by a prescriber to be filled,
- 26 compounded, or dispensed. Prescribing is limited to a prescriber.
- 27 An order transmitted in other than written form shall be

- 1 ELECTRONICALLY recorded, PRINTED, or written and immediately dated
- 2 by the pharmacist, and that record constitutes the original
- 3 prescription. In a health facility or agency licensed under article
- 4 17 or other medical institution, an order for a drug or device in
- 5 the patient's chart constitutes for the purposes of this definition
- 6 the original prescription. Subject to section 17751(2),
- 7 prescription includes, but is not limited to, an order for a drug,
- 8 not including a controlled substance as defined in section 7104
- 9 except under circumstances described in section 17763(e), written
- 10 and signed or transmitted by FACSIMILE, ELECTRONIC TRANSMISSION, OR
- 11 other means of communication by a physician prescriber licensed to
- 12 practice in a state other than Michigan.
- 13 (4) "Prescription drug" means 1 or more of the following:
- 14 (a) A drug dispensed pursuant to a prescription.
- 15 (b) A drug bearing the federal legend "CAUTION: federal law
- 16 prohibits dispensing without prescription".
- 17 (c) A drug designated by the board as a drug that may only be
- 18 dispensed pursuant to a prescription.
- 19 Sec. 17709. (1) "SIGN" MEANS TO AFFIX ONE'S SIGNATURE MANUALLY
- 20 TO A DOCUMENT OR TO USE AN ELECTRONIC SIGNATURE WHEN TRANSMITTING A
- 21 PRESCRIPTION ELECTRONICALLY.
- 22 (2) -(1) "Substitute" means to dispense, without the
- 23 prescriber's authorization, a different drug in place of the drug
- 24 prescribed.
- 25 (3) -(2) "Wholesale distributor" means a person, other than a
- 26 manufacturer, who supplies, distributes, sells, offers for sale,
- 27 barters, or otherwise disposes of, to other persons for resale,

- 1 compounding, or dispensing, a drug or device salable on
- 2 prescription only that the distributor has not prepared, produced,
- 3 derived, propagated, compounded, processed, packaged, or
- 4 repackaged, or otherwise changed the container or the labeling
- 5 thereof.
- 6 Sec. 17745. (1) Except as otherwise provided in this
- 7 subsection, a prescriber who wishes to dispense prescription drugs
- 8 shall obtain from the board a drug control license for each
- 9 location in which the storage and dispensing of prescription drugs
- 10 occur. A drug control license is not necessary if the dispensing
- 11 occurs in the emergency department, emergency room, or trauma
- 12 center of a hospital licensed under article 17 or if the dispensing
- 13 involves only the issuance of complimentary starter dose drugs.
- 14 (2) A dispensing prescriber shall dispense prescription drugs
- 15 only to his or her own patients.
- 16 (3) A dispensing prescriber shall include in a patient's chart
- 17 or clinical record a complete record, including prescription drug
- 18 names, dosages, and quantities, of all prescription drugs dispensed
- 19 directly by the dispensing prescriber or indirectly under his or
- 20 her delegatory authority. If prescription drugs are dispensed under
- 21 the prescriber's delegatory authority, the delegatee who dispenses
- 22 the prescription drugs shall initial the patient's chart, clinical
- 23 record, or log of prescription drugs dispensed. In a patient's
- 24 chart or clinical record, a dispensing prescriber shall distinguish
- 25 between prescription drugs dispensed to the patient and
- 26 prescription drugs prescribed for the patient. A dispensing
- 27 prescriber shall retain information required under this subsection

- 1 for not less than 5 years after the information is entered in the
- patient's chart or clinical record.
- 3 (4) A dispensing prescriber shall store prescription drugs
- 4 under conditions that will maintain their stability, integrity, and
- 5 effectiveness and will assure that the prescription drugs are free
- 6 of contamination, deterioration, and adulteration.
- 7 (5) A dispensing prescriber shall store prescription drugs in
- 8 a substantially constructed, securely lockable cabinet. Access to
- 9 the cabinet shall be limited to individuals authorized to dispense
- 10 prescription drugs in compliance with this part and article 7.
- 11 (6) Unless otherwise requested by a patient, a dispensing
- 12 prescriber shall dispense a prescription drug in a safety closure
- 13 container that complies with the poison prevention packaging act of
- 14 1970, Public Law 91-601, 84 Stat. 1670.
- 15 (7) A dispensing prescriber shall dispense a drug in a
- 16 container that bears a label containing all of the following
- 17 information:
- 18 (a) The name and address of the location from which the
- 19 prescription drug is dispensed.
- 20 (b) The patient's name and record number.
- (c) The date the prescription drug was dispensed.
- 22 (d) The prescriber's name.
- (e) The directions for use.
- 24 (f) The name and strength of the prescription drug.
- 25 (q) The quantity dispensed.
- 26 (h) The expiration date of the prescription drug or the
- 27 statement required under section 17756.

- 1 (8) A dispensing prescriber who dispenses a complimentary
- 2 starter dose drug to a patient shall give the patient at least all
- 3 of the following information, either by dispensing the
- 4 complimentary starter dose drug to the patient in a container that
- 5 bears a label containing the information or by giving the patient a
- 6 written document which may include, but is not limited to, a
- 7 preprinted insert that comes with the complimentary starter dose
- 8 drug, that contains the information:
- 9 (a) The name and strength of the complimentary starter dose
- 10 drug.
- 11 (b) Directions for the patient's use of the complimentary
- 12 starter dose drug.
- 13 (c) The expiration date of the complimentary starter dose drug
- 14 or the statement required under section 17756.
- 15 (9) The information required under subsection (8) is in
- 16 addition to, and does not supersede or modify, other state or
- 17 federal law regulating the labeling of prescription drugs.
- 18 (10) In addition to meeting the requirements of this part, a
- 19 dispensing prescriber who dispenses controlled substances shall
- 20 comply with section 7303a.
- 21 (11) The board may periodically inspect locations from which
- 22 prescription drugs are dispensed.
- 23 (12) The act, task, or function of dispensing prescription
- 24 drugs shall be delegated only as provided in section 16215 and this
- **25** part.
- 26 (13) A supervising physician may delegate in writing to a
- 27 pharmacist practicing in a hospital pharmacy within a hospital

- 1 licensed under article 17 the receipt of complimentary starter dose
- 2 drugs other than controlled substances as defined by article 7 or
- 3 federal law. When the delegated receipt of complimentary starter
- 4 dose drugs occurs, both the pharmacist's name and the supervising
- 5 physician's name shall be used, recorded, or otherwise indicated in
- 6 connection with each receipt. A pharmacist described in this
- 7 subsection may dispense a prescription for complimentary starter
- 8 dose drugs written or transmitted by FACSIMILE, ELECTRONIC
- 9 TRANSMISSION, OR other means of communication by a prescriber.
- 10 (14) As used in this section, "complimentary starter dose"
- 11 means a prescription drug packaged, dispensed, and distributed in
- 12 accordance with state and federal law that is provided to a
- 13 dispensing prescriber free of charge by a manufacturer or
- 14 distributor and dispensed free of charge by the dispensing
- 15 prescriber to his or her patients.
- 16 Sec. 17751. (1) A pharmacist shall not dispense a drug
- 17 requiring a prescription under the federal act or a law of this
- 18 state except under authority of an original prescription or an
- 19 equivalent record of an original prescription approved by the
- 20 board.
- 21 (2) A pharmacist may dispense a prescription written and
- 22 signed or transmitted by FACSIMILE, ELECTRONIC TRANSMISSION, OR
- 23 other means of communication by a physician prescriber in a state
- 24 other than Michigan, but not including a prescription for a
- 25 controlled substance as defined in section 7104 except under
- 26 circumstances described in section 17763(e), only if the pharmacist
- 27 in the exercise of his or her professional judgment determines all

- 1 of the following:
- 2 (a) That the prescription was issued pursuant to an existing
- 3 physician-patient relationship.
- 4 (b) That the prescription is authentic.
- 5 (c) That the prescribed drug is appropriate and necessary for
- 6 the treatment of an acute, chronic, or recurrent condition.
- 7 (3) A pharmacist or a prescriber shall dispense a prescription
- 8 only if the prescription falls within the scope of practice of the
- 9 prescriber.
- 10 (4) A pharmacist shall not knowingly dispense a prescription
- 11 after the death of the prescriber or patient.
- 12 SEC. 17754. (1) EXCEPT AS OTHERWISE PROVIDED UNDER ARTICLE 7
- 13 AND THE FEDERAL ACT, A PRESCRIPTION MAY BE TRANSMITTED
- 14 ELECTRONICALLY AS LONG AS THE PRESCRIPTION IS TRANSMITTED IN
- 15 COMPLIANCE WITH THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY
- 16 ACT OF 1996, PUBLIC LAW 104-191, OR REGULATIONS PROMULGATED UNDER
- 17 THAT ACT, 45 CFR PARTS 160 AND 164, BY A PRESCRIBER OR THE
- 18 PRESCRIBER'S AUTHORIZED AGENT AND THE DATA ARE NOT ALTERED OR
- 19 MODIFIED IN THE TRANSMISSION PROCESS. THE ELECTRONICALLY
- 20 TRANSMITTED PRESCRIPTION SHALL INCLUDE ALL OF THE FOLLOWING
- 21 INFORMATION:
- 22 (A) THE NAME, ADDRESS, AND TELEPHONE NUMBER OF THE PRESCRIBER.
- 23 (B) THE FULL NAME OF THE PATIENT FOR WHOM THE PRESCRIPTION IS
- 24 ISSUED.
- 25 (C) AN ELECTRONIC SIGNATURE OR OTHER IDENTIFIER THAT
- 26 SPECIFICALLY IDENTIFIES AND AUTHENTICATES THE PRESCRIBER OR THE
- 27 PRESCRIBER'S AUTHORIZED AGENT.

- 1 (D) THE TIME AND DATE OF THE TRANSMISSION.
- 2 (E) THE IDENTITY OF THE PHARMACY INTENDED TO RECEIVE THE
- 3 TRANSMISSION.
- 4 (F) ANY OTHER INFORMATION REQUIRED BY THE FEDERAL ACT OR STATE
- 5 LAW.
- 6 (2) THE ELECTRONIC EQUIPMENT OR SYSTEM UTILIZED IN THE
- 7 TRANSMISSION AND COMMUNICATION OF PRESCRIPTIONS SHALL PROVIDE
- 8 ADEQUATE CONFIDENTIALITY SAFEGUARDS AND BE MAINTAINED TO PROTECT
- 9 PATIENT CONFIDENTIALITY AS REQUIRED UNDER ANY APPLICABLE FEDERAL
- 10 AND STATE LAW AND TO ENSURE AGAINST UNAUTHORIZED ACCESS. THE
- 11 ELECTRONIC TRANSMISSION OF A PRESCRIPTION SHALL BE COMMUNICATED IN
- 12 A RETRIEVABLE, RECOGNIZABLE FORM ACCEPTABLE TO THE INTENDED
- 13 RECIPIENT. THE ELECTRONIC FORM UTILIZED IN THE TRANSMISSION OF A
- 14 PRESCRIPTION SHALL NOT INCLUDE "DISPENSE AS WRITTEN" OR "D.A.W." AS
- 15 THE DEFAULT SETTING.
- 16 (3) PRIOR TO DISPENSING A PRESCRIPTION THAT IS ELECTRONICALLY
- 17 TRANSMITTED, THE PHARMACIST SHALL EXERCISE PROFESSIONAL JUDGMENT
- 18 REGARDING THE ACCURACY, VALIDITY, AND AUTHENTICITY OF THE
- 19 TRANSMITTED PRESCRIPTION.
- 20 (4) AN ELECTRONICALLY TRANSMITTED PRESCRIPTION THAT MEETS THE
- 21 REQUIREMENTS OF THIS SECTION IS THE ORIGINAL PRESCRIPTION.
- 22 Sec. 17763. In addition to the grounds set forth in part 161,
- 23 the disciplinary subcommittee may fine, reprimand, or place a
- 24 pharmacist licensee on probation, or deny, limit, suspend, or
- 25 revoke the license of a pharmacist or order restitution or
- 26 community service for a violation or abetting in a violation of
- 27 this part or rules promulgated under this part, or for 1 or more of

- 1 the following grounds:
- 2 (a) Permitting the dispensing of prescriptions by an
- 3 individual who is not a pharmacist, pharmacist intern, or
- 4 dispensing prescriber.
- 5 (b) Permitting the dispensing of prescriptions by a pharmacist
- 6 intern, except in the presence and under the personal charge of a
- 7 pharmacist.
- 8 (c) Selling at auction drugs in bulk or in open packages
- 9 unless the sale has been approved in accordance with rules of the
- 10 board.
- 11 (d) Promoting a prescription drug to the public in any manner.
- 12 (e) In addition to the prohibition contained in section
- 13 7405(1)(e), dispensing a prescription for a controlled substance as
- 14 defined in section 7104 that is written and signed or transmitted
- 15 by FACSIMILE, ELECTRONIC TRANSMISSION, OR OTHER MEANS OF
- 16 COMMUNICATION BY a physician prescriber in a state other than
- 17 Michigan, unless the prescription is issued by a physician
- 18 prescriber who resides adjacent to the land border between this
- 19 state and an adjoining state or resides in Illinois or Minnesota
- 20 and who is authorized under the laws of that state to practice
- 21 medicine or osteopathic medicine and surgery and to prescribe
- 22 controlled substances and whose practice may extend into this
- 23 state, but who does not maintain an office or designate a place to
- 24 meet patients or receive calls in this state.