SUBSTITUTE FOR

HOUSE BILL NO. 5436

A bill to amend 1978 PA 368, entitled

"Public health code,"

by amending sections 17703, 17704, 17707, 17708, 17709, 17744, 17751, and 17757 (MCL 333.17703, 333.17704, 333.17707, 333.17708, 333.17709, 333.17744, 333.17751, and 333.17757), sections 17703, 17707, 17708, 17751, and 17757 as amended by 2023 PA 97, section 17704 as amended by 2018 PA 41, section 17709 as amended by 2020 PA 142, and section 17744 as amended by 2020 PA 136, and by adding section 17744g.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 17703. (1) "Deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from 1 person to another.

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

(3) "Dispense" means the preparation, compounding, packaging, or labeling of a drug pursuant to ~~a~~ **any of the following:**

(a) A prescription. ~~or other~~

(b) An authorization issued by a prescriber. ~~or pursuant to section~~

(c) Section 17724a or 17744f.

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

(5) Except as otherwise provided in section 17780, "distribute" or "distribution" means to sell, offer for sale, deliver, offer to deliver, broker, give away, or transfer a drug, whether by passage of title or physical movement. The term does not include any of the following:

(a) Dispensing or administering a drug.

(b) The delivery of a drug, or offering to deliver a drug, by a common carrier in the usual course of business as a common carrier.

(c) The delivery of a drug via an automated device under section 17760.

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

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

(b) A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or

other animals.

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

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

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

(8) "Electronically transmitted prescription" means the communication of an original prescription or refill authorization by electronic means including computer to computer, computer to facsimile machine, or email transmission that contains the same information it contained when the prescriber or ~~his or her~~ **the prescriber's** agent transmitted the prescription. Electronically transmitted prescription does not include a prescription or refill authorization transmitted by telephone or facsimile machine.

(9) "Emergency contraceptive" means a drug approved by the FDA to prevent pregnancy as soon as possible following unprotected sexual intercourse or a known or suspected contraceptive failure.

Sec. 17704. (1) "Federal act" means the federal food, drug, and cosmetic act, 21 USC 301 to ~~399h.~~**399i.**

(2) "Food and Drug Administration" or "FDA" means the United States Food and Drug Administration.

(3) "Generic name" means the established or official name of a drug or drug product.

(4) "Harmful drug" means a drug intended for use by human beings that is harmful because of its toxicity, habit-forming

nature, or other potential adverse effect; the method of its use; or the collateral measures necessary to its safe and effective use and that is designated as harmful by a rule promulgated under this part.

(5) "Hormonal contraceptive patch" means a transdermal patch applied to the skin of an individual that releases a drug composed of a combination of hormones that is approved by the FDA to prevent pregnancy.

(6) ~~(5)~~ "Interchangeable biological drug product" means either of the following, as applicable:

(a) A biological drug product that is licensed by the FDA and that the FDA has determined meets the standards for interchangeability under 42 USC 262(k)(4).

(b) Until March 23, 2021, a biological drug product that the FDA has determined to be therapeutically equivalent as set forth in "Approved Drug Products with Therapeutic Equivalence Evaluations", an FDA publication that is commonly referred to as the "Orange Book".

(7) ~~(6)~~ "Internship" means an educational program of professional and practical experience for an intern.

Sec. 17707. (1) "Parent pharmacy" means a pharmacy that operates a remote pharmacy through a telepharmacy system.

(2) "Personal charge" means the immediate physical presence of a pharmacist or dispensing prescriber.

(3) "Pharmacist" means an individual who is licensed under this article to engage in the practice of pharmacy.

(4) "Pharmacist in charge" or "PIC" means the pharmacist who is designated by a pharmacy, manufacturer, wholesale distributor, or wholesale distributor-broker as its pharmacist in charge under

section 17748(2).

(5) "Pharmacist intern" or "intern" means an individual who satisfactorily completes the requirements set forth in rules promulgated by the department in consultation with the board and is licensed by the board for the purpose of obtaining instruction in the practice of pharmacy from a preceptor approved by the board.

(6) "Pharmacy" means a facility or part of a facility that is licensed under this part to dispense prescription drugs or prepare prescription drugs for delivery or distribution. Pharmacy does not include the office of a dispensing prescriber or an automated device. For the purpose of a duty placed on a pharmacy under this part, "pharmacy" means the person to which the pharmacy license is issued, unless otherwise specifically provided.

(7) "Pharmacy technician" means an individual who is required to hold a health profession subfield license under this part to serve as a pharmacy technician.

(8) "Practice of pharmacy" means a health service, the clinical application of which includes the encouragement of safety and efficacy in the prescribing, dispensing, administering, and use of drugs and related articles for the prevention of illness, and the maintenance and management of health. Practice of pharmacy includes the direct or indirect provision of professional functions and services associated with the practice of pharmacy. Professional functions associated with the practice of pharmacy include the following:

(a) The interpretation and evaluation of the prescription.

(b) Drug product selection.

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

(d) The maintenance of legally required records.

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

(f) Ordering and administering qualified immunizing agents in accordance with section 17724.

(g) Ordering and administering qualified laboratory tests in accordance with section 17724a.

(h) Issuing prescriptions for hormonal contraceptive patches, self-administered hormonal contraceptives, emergency contraceptives, and vaginal ring hormonal contraceptives in accordance with section 17744g.

Sec. 17708. (1) "Preceptor" means a pharmacist approved by the board to direct the training of an intern in an approved pharmacy.

(2) "Prescriber" means a licensed dentist; a licensed doctor of medicine; a licensed doctor of osteopathic medicine and surgery; a licensed doctor of podiatric medicine and surgery; a licensed physician's assistant; subject to part 174, a licensed optometrist; subject to section 17211a, an advanced practice registered nurse; a licensed veterinarian; subject to subsection (7), a registered professional nurse who holds a specialty certification as a nurse anesthetist under section 17210 when ~~he or she is~~ engaging in the practice of nursing and providing the anesthesia and analgesia services described in section 17210(3); or any other licensed health professional acting under the delegation and using, recording, or otherwise indicating the name of the delegating licensed doctor of medicine or licensed doctor of osteopathic medicine and surgery. As used in this subsection:

(a) "Advanced practice registered nurse" means that term as

defined in section 17201 and includes a licensed advanced practice registered nurse.

(b) "License" means that term as defined in section 16106 and includes an authorization issued under the laws of another state or province of Canada to practice a profession described in this subsection in that state or province of Canada where practice would otherwise be unlawful.

(3) "Prescription" means an order by a prescriber to fill, compound, or dispense a drug or device written and signed; written or created in an electronic format, signed, and transmitted by facsimile; or transmitted electronically or by other means of communication. An order transmitted in other than written or hard-copy form must be electronically recorded, printed, or written and immediately dated by the pharmacist, and that record is considered the original prescription. In a health facility or agency licensed under article 17 or other medical institution, an order for a drug or device in the patient's chart is considered for the purposes of this definition the original prescription. For purposes of this part, prescription also includes a standing order issued under section 17744e **and an order to dispense a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive issued by a pharmacist under section 17744g.** Subject to section 17751(2) and (5), prescription includes, but is not limited to, an order for a drug, not including a controlled substance except under circumstances described in section 17763(e), written and signed; written or created in an electronic format, signed, and transmitted by facsimile; or transmitted electronically or by other means of communication by a prescriber in another state or province of

Canada.

(4) Subject to subsection (5), "prescription drug" means a drug to which 1 or more of the following apply:

(a) The drug is dispensed pursuant to a prescription.

(b) The drug bears the federal legend "CAUTION: federal law prohibits dispensing without prescription" or "Rx only".

(c) The drug is designated by the board as a drug that may only be dispensed pursuant to a prescription.

(5) For purposes of this part, prescription drug also includes a drug dispensed pursuant to section 17724a or 17744f.

(6) "Remote pharmacy" means a pharmacy described in sections 17742a and 17742b.

(7) The authority of a registered professional nurse who holds a specialty certification as a nurse anesthetist under section 17210 to prescribe pharmacological agents is limited to pharmacological agents for administration to patients as described in section 17210(3)(b), (c), or (d). Subsection (2) does not require new or additional third party reimbursement or mandated worker's compensation benefits for anesthesia and analgesia services provided under section 17210(3) by a registered professional nurse who holds a specialty certification as a nurse anesthetist under section 17210.

Sec. 17709. **(1) "Self-administered hormonal contraceptive" means a drug composed of a single hormone or combination of hormones that is approved by the FDA to prevent pregnancy and that the individual to whom the drug is prescribed may take orally, inject, or otherwise self-administer.**

(2) ~~(1)~~ "Sign" means to affix one's signature manually to a document or to use an electronic signature when transmitting a

prescription electronically.

(3) ~~(2)~~ "Sterile pharmaceutical" means a dosage form of a drug that is essentially free from living microbes and chemical or physical contamination to the point at which it poses no present risk to the patient, in accordance with USP standards. As used in this subsection, "dosage form" includes, but is not limited to, parenteral, injectable, and ophthalmic dosage forms.

(4) ~~(3)~~ "Substitute" means to dispense, without the prescriber's authorization, a different drug in place of the drug prescribed.

(5) ~~(4)~~ "Surveillance system" means a real-time, continuous audio and visual camera system that connects a pharmacist at a parent pharmacy with a remote pharmacy for the purposes of providing oversight and security surveillance.

(6) ~~(5)~~ "Telepharmacy system" means an interoperable computer system that meets all of the following requirements:

(a) Shares real-time data and uses a real-time audio and video link to connect a pharmacist at a parent pharmacy with a remote pharmacy operated by the parent pharmacy.

(b) Uses a camera that is of sufficient quality and resolution to allow a pharmacist at a parent pharmacy who is reviewing a prescription to visually identify the markings on tablets and capsules at the remote pharmacy.

(7) ~~(6)~~ "USP standards" means the pharmacopeial standards for drug substances, dosage forms, and compounded preparations based on designated levels of risk as published in the official compendium.

(8) ~~(7)~~ "Wholesale distributor" means a person, other than a manufacturer or wholesale distributor-broker, that supplies, distributes, sells, offers for sale, barters, or otherwise disposes

of, to other persons for resale, compounding, or dispensing, a drug or device salable on prescription only that the distributor has not prepared, produced, derived, propagated, compounded, processed, packaged, or repackaged, or otherwise changed the container or the labeling of the drug or device. A wholesale distributor does not include a pharmacy unless the pharmacy meets the requirements of section 17748f.

(9) ~~(8)~~ "Wholesale distributor-broker" means a person that meets both of the following:

(a) The person facilitates the delivery or trade of a drug or device salable on prescription only, other than a controlled substance, between pharmacies, or between a pharmacy and a qualified pharmacy as that term is defined in section 17748e, for the purpose of filling a prescription for an identified patient.

(b) The person does not take possession or ownership of a drug or device salable on prescription only or coordinate warehousing of the drug or device.

Sec. 17744. (1) A prescriber may designate an agent to act on behalf of or at the discretion of that prescriber. A designation of an agent by a prescriber under this section is not required to be in writing to be a valid designation. If a designation of an agent by a prescriber under this section is contained in a written document, the prescriber or the agent may transmit that document to a pharmacy that will dispense a prescription issued by that prescriber.

(2) ~~Only~~ **Except as otherwise provided in this part, only** a prescriber **who is** acting within the scope of ~~his or her~~ **the prescriber's** practice may issue a prescription. An agent may prepare and transmit a prescription that has been signed by the

prescriber, including a signature that meets the requirements of section 17754 or 17754a. The prescriber issuing a prescription and the pharmacist **issuing a prescription in accordance with this part or** dispensing a drug or device under a prescription is responsible for all of the requirements of state and federal law, rules, and regulations regarding the issuance of prescriptions and dispensing of drugs or devices under prescriptions.

(3) A prescriber or ~~his or her~~ **the prescriber's** agent may transmit to a pharmacy a prescription that is contained within a patient's chart in a health facility or agency licensed under article 17 or other medical institution. A prescription that is contained within a patient's chart in a health facility or agency licensed under article 17 or other medical institution and that is created in an electronic format may contain more than 6 prescriptions and may contain prescriptions for schedule 3 ~~through~~ **to** 5 controlled substances and noncontrolled substances on the same form.

Sec. 17744g. (1) Subject to the rules promulgated under this section, a pharmacist may issue a prescription for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive to an individual, regardless of the individual's age and regardless of whether the individual has evidence of a previous prescription from a prescriber for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive.

(2) By 18 months after the effective date of the amendatory act that added this section, the department, in consultation with the board, shall promulgate rules to implement this section. The

rules must establish a standard procedure for issuing a prescription for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, and a vaginal ring hormonal contraceptive under this section. The rules must also prohibit a pharmacist from issuing a prescription for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive to an individual described in subsection (1) if the individual has not completed the self-screening risk assessment tool developed under subsection (3) and must require that a pharmacist comply with all of the following:

(a) Complete a training program that is approved by the board for issuing a prescription for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive.

(b) Provide the self-screening risk assessment tool that is developed under subsection (3) to an individual described in subsection (1) before issuing a prescription for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive to the individual.

(c) Upon issuing a prescription for the hormonal contraceptive patch, self-administered hormonal contraceptive, emergency contraceptive, or vaginal ring hormonal contraceptive to an individual described in subsection (1), refer the individual to the individual's primary care physician, or if the individual does not have a primary care physician, to another licensed health professional that the pharmacist considers appropriate.

(d) Provide an individual described in subsection (1) with a

written record of the hormonal contraceptive patch, self-administered hormonal contraceptive, emergency contraceptive, or vaginal ring hormonal contraceptive for which the individual is issued the prescription and advise the individual to consult with a physician or other licensed health professional.

(e) If an individual described in subsection (1) has not had a physical examination in the previous 12 months, refer the individual to the individual's primary care provider for a physical examination after issuing a prescription for the hormonal contraceptive patch, self-administered hormonal contraceptive, emergency contraceptive, or vaginal ring hormonal contraceptive to the individual.

(f) Dispense the hormonal contraceptive patch, self-administered hormonal contraceptive, emergency contraceptive, or vaginal ring hormonal contraceptive to an individual described in subsection (1) as soon as practicable after issuing the prescription for the hormonal contraceptive patch, self-administered hormonal contraceptive, emergency contraceptive, or vaginal ring hormonal contraceptive to the individual, or transmit the prescription to another pharmacy of the individual's choice if authorized pursuant to rules promulgated by the department.

(3) The department, in consultation with the board, shall by rule develop a self-screening risk assessment tool to be used by an individual who is seeking a prescription for a hormonal contraceptive patch, a self-administered hormonal contraceptive, an emergency contraceptive, or a vaginal ring hormonal contraceptive under this section.

Sec. 17751. (1) Except as otherwise provided in sections 17724a and 17744f, a pharmacist shall not dispense a drug requiring

a prescription under the federal act or a law of this state except under authority of an original prescription or an equivalent record of an original prescription approved by the board. A pharmacist described in section 17742b(2) may dispense a drug pursuant to an original prescription received at a remote pharmacy if the pharmacist receives, reviews, and verifies an exact digital image of the prescription received at the remote pharmacy before the drug is dispensed at the remote pharmacy.

(2) Subject to this subsection and subsections (1) and (5), a pharmacist may dispense a drug or device pursuant to a prescription written and signed; written or created in an electronic format, signed, and transmitted by facsimile; or transmitted electronically or by other means of communication by a prescriber in another state or province of Canada, but not including a prescription for a controlled substance except under circumstances described in section 17763(e). Before dispensing a drug or device pursuant to a prescription under this subsection, the pharmacist, in the exercise of ~~his or her~~ **the pharmacist's** professional judgment, must determine all of the following:

(a) Except as otherwise authorized under section 5110, 17744a, or 17744b, if the prescriber is not a veterinarian, that the prescription was issued pursuant to an existing prescriber-patient relationship.

(b) That the prescription is authentic.

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

(3) A pharmacist or a prescriber shall dispense a drug or device pursuant to a prescription only if the prescription falls within the scope of practice of the prescriber **or if the**

prescription was issued by a pharmacist in accordance with this part.

(4) A pharmacist shall not knowingly dispense a drug or device pursuant to a prescription after the death of the ~~prescriber or~~ patient.

(5) A pharmacist shall not dispense a drug or device pursuant to 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 any of the following:

(a) A prescription that is transmitted by a computer to a facsimile machine if that prescription complies with section 17754 or 17754a.

(b) A prescription that is received by a remote pharmacy and made available to a pharmacist described in section 17742b(2) for review and verification in the manner required under subsection (1).

(6) After consultation with and agreement from the prescriber, a pharmacist may add or change a patient's address, a dosage form, a drug strength, a drug quantity, a direction for use, or an issue date with regard to a prescription. A pharmacist shall note the details of the consultation and agreement required under this subsection on the prescription or, if the drug is dispensed at a remote pharmacy, on the digital image of the prescription described in subsection (1), and shall maintain that documentation with the prescription as required in section 17752. A pharmacist shall not change the patient's name, controlled substance prescribed unless authorized to dispense a lower cost generically equivalent drug product under section 17755, or the prescriber's signature with

regard to a prescription.

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

(8) If, after consulting with a patient, a pharmacist determines in the exercise of ~~his or her~~ **the pharmacist's** professional judgment that dispensing additional quantities of a prescription drug is appropriate for the patient, the pharmacist may dispense, at one time, additional quantities of the prescription drug up to the total number of dosage units authorized by the prescriber on the original prescription for the patient and any refills of the prescription. Except for a controlled substance included in schedule 5 that does not contain an opioid, this subsection does not apply to a prescription for a controlled substance.

(9) Notwithstanding any provision of this section, a pharmacist who receives a prescription under subsection (2) from an advanced practice registered nurse prescriber or physician's

assistant prescriber in another state or province of Canada may dispense the drug or device without determining whether the advanced practice registered nurse prescriber or physician's assistant prescriber is authorized under the laws of the other state or province of Canada to issue the prescription.

Sec. 17757. (1) When a pharmacist engaged in the business of selling drugs receives a prescription, the pharmacist may, or, when the pharmacist receives a request made in person or by telephone, the pharmacist shall provide the current selling price of a drug dispensed by that pharmacy or comparative current selling prices of generic and brand name drugs or biosimilar drug products dispensed by that pharmacy. If information is provided under this subsection, it must be provided before a drug is dispensed. A person that makes a request for or receives price information under this subsection is not obligated to purchase the drug for which the price or comparative prices are requested or received. A pharmacy or a pharmacist described in this subsection shall not enter into a contract that prohibits the disclosure of the information described in this subsection.

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

(3) The notice required under subsection (2) must be in substantially the following form:

NOTICE TO CONSUMERS

ABOUT PRESCRIPTION DRUGS

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

Every pharmacy has the current selling prices of both generic 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.

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

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

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

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

(5) The department shall provide a copy of the notice required under subsection (2) to each licensee. The department shall provide additional copies 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.

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

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

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

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

(d) The quantity dispensed, if applicable.

(e) The name and address of the pharmacy.

(f) The serial number of the prescription, a reference to the standing order issued under section 17744e, or, if the prescription drug is dispensed pursuant to section 17724a or 17744f, a reference to the applicable section.

(g) The date the prescription was originally dispensed, if applicable.

(h) The name of the prescriber or, if prescribed under the prescriber's delegatory authority, the name of the delegatee. If the prescription drug is dispensed pursuant to section 17744f, the name of the original prescriber and the pharmacist dispensing the prescription drug. If the prescription drug is dispensed pursuant to section 17724a, the name of the pharmacist dispensing the prescription drug. **If the prescription was issued under section 17744g, the name of the pharmacist issuing the prescription.**

(i) Except as otherwise authorized under section 5110, 17744a, 17744b, or 17744e, the name of the patient for whom the drug was prescribed or dispensed.

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

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

(8) The department, in consultation with the board, may promulgate rules to implement this section.

Enacting section 1. This amendatory act does not take effect unless House Bill No. 5435 of the 102nd Legislature is enacted into law.