HOUSE BILL NO. 5655

December 15, 2021, Introduced by Reps. Hope, Breen, Rogers, Morse, Cavanagh, Kuppa, Weiss, Bolden, Pohutsky, Neeley, Anthony, Brixie, Hood, Stone, Puri and Aiyash and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled

"Public health code,"

by amending sections 17704, 17707, 17708, 17709, and 17744 (MCL 333.17704, 333.17707, 333.17708, 333.17709, and 333.17744), section 17704 as amended by 2018 PA 41, sections 17707 and 17709 as amended by 2020 PA 142, section 17708 as amended by 2021 PA 53, and section 17744 as amended by 2020 PA 136, and by adding section 17744g.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

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, by the individual or by a physician or other licensed health professional, that releases a drug composed of a combination of hormones that is approved by the Food and Drug Administration 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~~ **Interpreting** and ~~evaluation of~~ **evaluating** the prescription.

(b) Drug product selection.

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

(d) ~~The maintenance of~~ **Maintaining** 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) Prescribing and dispensing hormonal contraceptive patches, self-administered hormonal contraceptives, and vaginal ring hormonal contraceptives under 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 any of the following:

(a) A licensed dentist.

(b) A licensed doctor of medicine.

(c) A licensed doctor of osteopathic medicine and surgery.

(d) A licensed doctor of podiatric medicine and surgery.

(e) A licensed physician's assistant.

(f) A licensed optometrist certified under part 174 to administer and prescribe therapeutic pharmaceutical agents.

(g) An advanced practice registered nurse as that term is defined in section 17201 who meets the requirements of section 17211a.

(h) A licensed veterinarian.

(i) 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). For purposes of this subdivision, 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).

(j) For purposes of subsection (3) and sections 17744(2), 17751(3), and 17757(6) only, prescriber includes a pharmacist who prescribes a hormonal contraceptive patch, self-administered hormonal contraceptive, or vaginal ring hormonal contraceptive under section 17744g.

(k) ~~(j)~~ 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.

(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. 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 physician prescriber, dentist prescriber, or veterinarian prescriber who is licensed to practice dentistry, medicine, osteopathic medicine and surgery, or veterinary medicine in another state.

(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 17744f.

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

(7) Subsection (2)(i) 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 combination of hormones that is approved by the Food and Drug Administration 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 a prescriber **who is** acting within the scope of his or her practice may issue a prescription. An agent may prepare and transmit a prescription that has been signed by ~~the~~ **a** prescriber **other than a pharmacist,** including a signature that meets the requirements of section 17754 or 17754a. The prescriber issuing a prescription and the pharmacist 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 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 prescribe and dispense a hormonal contraceptive patch, self-administered hormonal contraceptive, or 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, self-administered hormonal contraceptive, or vaginal ring hormonal contraceptive.

(2) The department, in consultation with the board, shall promulgate rules to establish a standard procedure for prescribing a hormonal contraceptive patch, self-administered hormonal contraceptive, and vaginal ring hormonal contraceptive under this section. The rules must comply with all of the following:

(a) The rules must require a pharmacist to comply with all of the following:

(*i*) Complete a training program that is approved by the board for prescribing a hormonal contraceptive patch, self-administered hormonal contraceptive, or vaginal ring hormonal contraceptive.

(*ii*) Provide the self-screening risk assessment tool that is developed by the department under subsection (3) to an individual described in subsection (1) before the pharmacist issues a prescription for a hormonal contraceptive patch, self-administered hormonal contraceptive, or vaginal ring hormonal contraceptive to the individual.

(*iii*) Upon prescribing and dispensing the hormonal contraceptive patch, self-administered hormonal contraceptive, or vaginal ring hormonal contraceptive to an individual described in subsection (1), refer the individual to the individual's physician or other licensed health professional.

(*iv*) Provide an individual who is described in subsection (1) with a written record of the hormonal contraceptive patch, self-administered hormonal contraceptive, or vaginal ring hormonal contraceptive prescribed for and dispensed to the individual and advise the individual to consult with a physician or other licensed health professional.

(*v*) Dispense the hormonal contraceptive patch, self-administered hormonal 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, or vaginal ring hormonal contraceptive to the individual.

(b) The rules must prohibit a pharmacist from prescribing a hormonal contraceptive patch, self-administered hormonal contraceptive, or vaginal ring hormonal contraceptive to an individual described in subsection (1) who has not used the self-screening risk assessment tool that is developed by the department under subsection (3).

(3) The department, in consultation with the American Congress of Obstetricians and Gynecologists, 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, self-administered hormonal contraceptive, or vaginal ring hormonal contraceptive under this section.

Enacting section 1. This amendatory act takes effect 90 days after the date it is enacted into law.