SENATE BILL NO. 630

October 31, 2019, Introduced by Senator BIZON and referred to the Committee on Health Policy and Human Services.

A bill to amend 1978 PA 368, entitled

"Public health code,"

by amending sections 16111, 16333, 17705, 17707, 17709, 17722, 17742, 17748, 17767, and 17768 (MCL 333.16111, 333.16333, 333.17705, 333.17707, 333.17709, 333.17722, 333.17742, 333.17748, 333.17767, and 333.17768), section 16111 as amended by 2006 PA 392, section 16333 as amended by 2014 PA 285, section 17705 as amended by 1986 PA 304, section 17707 as amended by 2016 PA 528, sections 17709 and 17742 as amended by 2014 PA 280, section 17748 as amended

by 2015 PA 169, section 17767 as amended by 1993 PA 79, and section 17768 as amended by 2014 PA 413, and by adding section 17748e.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

Sec. 16111. (1) This part applies to health professions, but, except for sections 16201, 16261, 16299, 16301, 16303, 16305, **and** 16307, ~~16309, and 16313,~~ does not apply to ~~a~~ **any of the following regulated under part 177:**

(a) A pharmacy. ~~,~~

(b) A dispensing prescriber. ~~, or~~

(c) A drug manufacturer. ~~or wholesaler who is regulated by part 177.~~

(d) A wholesale distributor.

(e) A wholesale distributor-broker.

(2) Except as otherwise provided by this article, this part controls over all other parts in this article.

(3) A part in this article does not prohibit a licensee under another part or other law of this state from performing activities and using designated titles authorized by a license issued to him or her under that other part or other law of this state.

(4) A part in this article does not prohibit a registrant under another part or other state law from using designated titles authorized by a registration issued to him or her under that other part or other state law.

(5) This article ~~shall~~ **does** not prohibit a licensee from advising a patient to seek professional services or advice from another person.

Sec. 16333. Fees for a person licensed or seeking licensure to engage in the practice of pharmacy or other practices regulated under part 177 are as follows:

(a)	Application processing fees:		
(*i*)	Pharmacist.....	$	20.00
(*ii*)	Pharmacy.....		35.00
(*iii*)	Drug control.....		20.00
(*iv*)	Manufacturer, ~~or wholesaler~~**wholesale distributor, or wholesale distributor-broker**.....		50.00
(*v*)	Pharmacy technician.....		25.00
(b)	Examination fees:		
	Jurisprudence examination.....		30.00
(c)	License fees, per year:		
(*i*)	Pharmacist.....		30.00
(*ii*)	Pharmacy.....		50.00
(*iii*)	Drug control.....		15.00
(*iv*)	Manufacturer, ~~or wholesaler~~**wholesale distributor, or wholesale distributor-broker**.....		25.00
(*v*)	Pharmacy technician.....		30.00
(d)	Temporary license for pharmacist.....		25.00
(e)	Limited license for pharmacist, per year...		15.00
(f)	Temporary license for pharmacy technician..		15.00
(g)	Limited license for pharmacy technician, per year.....		10.00

Sec. 17705. (1) "Label" means a display of written, printed, or graphic matter on the immediate container of a drug or device, but does not include package liners. A requirement made by or under authority of this part that a word, statement, or other information appear on the label is not complied with unless the word, statement, or other information appears on the outside container or wrapper of the retail package of the drug or device as displayed for sale or is easily legible through an outside container or

wrapper.

(2) "Labeling" means the labels and other written, printed, or graphic matter on a drug or device or its container or wrapper, or accompanying the drug or device.

(3) "License" in addition to the definition in section 16106 means a pharmacy license, drug control license, or a manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-broker** of drugs or devices license.

Sec. 17707. (1) "Personal charge" means the immediate physical presence of a pharmacist or dispensing prescriber.

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

(3) "Pharmacist in charge" or "PIC" means the pharmacist who is designated by a pharmacy, manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-broker** as its pharmacist in charge under section 17748(2).

(4) "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.

(5) "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.

(6) "Pharmacy technician" means an individual who is required

to hold a health profession subfield license under this part to serve as a pharmacy technician.

(7) "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.

Sec. 17709. (1) "Sign" means to affix one's signature manually to a document or to use an electronic signature when transmitting a prescription electronically.

(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.

(3) "Substitute" means to dispense, without the prescriber's

authorization, a different drug in place of the drug prescribed.

(4) "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.

(5) "Wholesale distributor" means a person, other than a manufacturer **or wholesale distributor-broker**, ~~who~~ **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.

(6) "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 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. 17722. In addition to the functions set forth in part 161, the board shall **do the following:**

(a) Regulate, control, and inspect the character and standard of pharmacy practice and of drugs and devices manufactured, distributed, prescribed, dispensed, administered, or issued in this state and procure samples and limit or prevent the sale of drugs and devices that do not comply with this part.

(b) Prescribe minimum criteria for the use of professional and technical equipment and references in the compounding and dispensing of drugs and devices.

(c) Grant a pharmacy license for each separate place of practice in which the compounding or dispensing of prescription drugs or devices, or both, or the receiving of prescription orders in this state is to be conducted.

(d) Grant a drug control license for the place of practice of a dispensing prescriber who meets the requirements for the license.

(e) Grant a license to a manufacturer, ~~or a~~ wholesale distributor, ~~of prescription drugs who~~ **or wholesale distributor-broker that** meets the requirements for the license.

Sec. 17742. (1) The board may require an applicant or the holder of a pharmacy, manufacturer's, ~~or~~ wholesale distributor's, **or wholesale distributor-broker's** license to fully disclose the identity of each partner, stockholder, officer, or member of the board of directors of the pharmacy, manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-broker**, as applicable.

(2) As used in this section and sections 17748, 17748a, **17748e**, and 17768, "applicant" means a person applying for a pharmacy, manufacturer's, ~~or~~ wholesale distributor's, **or wholesale distributor-broker's** license under this article. Applicant includes only 1 or more of the following:

(a) An individual, if the person applying is an individual.

(b) All partners, including limited partners, if the person applying is a partnership.

(c) All stockholders, officers, and members of the board of directors, if the person applying is a privately held corporation.

Sec. 17748. (1) ~~To~~ **Except for a qualified pharmacy as that**

term is defined in section 17748e, to do business in this state, a pharmacy, manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-broker,** whether or not located in this state, must be licensed under this part. To do business in this state, a person that provides compounding services must be licensed as a pharmacy or manufacturer under this part and, if a pharmacy, authorized to provide compounding services under this section and sections 17748a and 17748b. To do business in this state, an outsourcing facility must be licensed as a pharmacy under this part. Licenses are renewable biennially.

(2) A pharmacy shall designate a pharmacist licensed in this state as the pharmacist in charge for the pharmacy. Except as otherwise provided in this subsection, a manufacturer shall designate a pharmacist licensed in or outside of this state as the pharmacist in charge for the manufacturer. Except as otherwise provided in this subsection, a wholesale distributor **or wholesale distributor-broker** shall designate a pharmacist licensed in or outside of this state as the pharmacist in charge for the wholesale distributor **or wholesale distributor-broker** or shall designate an employee with the appropriate education or experience, or both, to assume responsibility for compliance with licensing requirements as facility manager for the wholesale distributor **or wholesale distributor-broker**. The pharmacy, manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-broker** and the individual designated as the PIC or facility manager under this subsection are jointly responsible for the pharmacy's, manufacturer's, ~~or~~ wholesale distributor's, **or wholesale distributor-broker's** compliance with this part and rules promulgated under this part. A person that is a manufacturer, ~~or~~ wholesale distributor, **or**

wholesale distributor-broker with respect to a device salable on prescription only but not with respect to any drug salable on prescription only is exempt from this subsection.

(3) Subject to this subsection, a pharmacist may be designated as the PIC for more than 1 pharmacy. A PIC described in this subsection shall work an average of at least 8 hours per week at each pharmacy for which he or she is the PIC. The pharmacy and the PIC shall maintain appropriate records and demonstrate compliance with this subsection upon the request of the board or its designee.

(4) A pharmacy, manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-broker** shall report to the department a change in ownership, management, location, or its PIC or facility manager designated under subsection (2) not later than 30 days after the change occurs.

(5) A pharmacist designated as the PIC for a pharmacy shall supervise the practice of pharmacy for the pharmacy. The duties of the PIC include, but are not limited to, the following:

(a) Supervision of all activities of pharmacy employees as they relate to the practice of pharmacy including the purchasing, storage, compounding, repackaging, dispensing, and distribution of drugs and devices to ensure that those activities are performed in compliance with this part and the rules promulgated under this part.

(b) Enforcement and oversight of policies and procedures applicable to the employees of the pharmacy for the procurement, storage, compounding, and dispensing of drugs and the communication of information to the patient in relation to drug therapy.

(c) Establishment and supervision of the method and manner for storage and safekeeping of pharmaceuticals, including maintenance

of security provisions to be used when the pharmacy is closed.

(d) Establishment and supervision of the record-keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs and devices.

(e) Establishment of policies and procedures for individuals who are delegated responsibilities for any of the tasks described in this subsection by the PIC.

(6) Except as otherwise provided in subsection (8), fingerprints for the following individuals ~~shall~~ **must** be submitted with an application for a new pharmacy, manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-broker** license in the same manner as required in section 16174 for the purpose of a criminal history check:

(a) If the application is from an individual, who is not a health professional licensed or otherwise authorized to engage in a health profession under this article or who is a health professional but was licensed or otherwise authorized to engage in his or her health profession under this article before October 1, 2008, fingerprints for that individual.

(b) If the application is from a partnership, fingerprints for all partners and any individual who will manage the day-to-day operations of the new pharmacy, manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-broker**.

(c) If the application is from a privately held corporation, fingerprints for any individual who will manage the day-to-day operations of the new pharmacy, manufacturer, or wholesale distributor. This subdivision only applies to a privately held corporation that in the aggregate owns fewer than 75 pharmacies, manufacturers, ~~or~~ wholesale distributors, **or wholesale distributor-**

brokers on the date the corporation submits its license application.

(7) The board, department, and department of state police shall conduct the criminal history check on the individuals described in subsection (6) in the same manner as described in section 16174.

(8) Subsection (6) does not apply if a criminal history check that meets the requirements of section 16174 has been obtained for the individuals described in subsection (6) within the 2 years preceding the date of the application for a new pharmacy, manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-broker** license under this part. To qualify for the exception under this subsection, an applicant shall submit proof of the previous criminal history check for each individual described in subsection (6), as applicable, with the application for a new pharmacy, manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-broker** license under this part. If the department or board determines that a criminal history check for an individual described in subsection (6) does not meet the requirements of section 16174 or was not obtained within the time period prescribed, fingerprints ~~shall~~ **must** be submitted for the individual as required under subsection (6).

(9) If, as authorized or required under this article, the department inspects or investigates an applicant for a new pharmacy license for a pharmacy that will provide compounding services or a compounding pharmacy, and the applicant or compounding pharmacy is located outside of this state, the applicant or compounding pharmacy shall reimburse the department for its expenses incurred in carrying out its authority or duty to inspect or investigate the

applicant or licensee under this article.

Sec. 17748e. (1) An out-of-state pharmacy that is not licensed under this part as a pharmacy may deliver or trade a drug or device salable on prescription only to a person located in this state only if the out-of-state pharmacy meets both of the following requirements:

(a) The out-of-state pharmacy holds a license in good standing as a pharmacy from the state in which it is located.

(b) The out-of-state pharmacy uses a wholesale distributor-broker that is licensed in this state to facilitate the transaction.

(2) Except as otherwise provided in this part, a pharmacy shall only deliver or trade a drug or device salable on prescription only that it receives from 1 or more of the following:

(a) A manufacturer.

(b) A wholesale distributor.

(c) Subject to subsection (3), a pharmacy.

(d) Subject to subsection (3), a qualified pharmacy.

(3) A drug salable on prescription only must not be delivered or traded between pharmacies, or between a pharmacy and a qualified pharmacy, unless all of the following are met:

(a) The drug is approved by the United States Food and Drug Administration.

(b) The drug is not a controlled substance.

(c) The drug is not expired at the time of the delivery or trade.

(d) The drug is delivered or traded in the original manufacturer's packaging, whether sealed or unsealed. If the original manufacturer's packaging is unsealed at the time of the

delivery or trade, the delivery or trade may include a quantity of the drug that is less than the quantity contained in the original manufacturer's packaging.

(e) If 1 of the pharmacies involved in the delivery or trade is a qualified pharmacy, the delivery or trade is intended to fill a prescription for an identified patient.

(4) A wholesale distributor-broker is not subject to disciplinary action under this part or liable in a civil action for personal injury or death resulting from a drug or device salable on prescription only that was delivered or traded by a pharmacy or qualified pharmacy under this section.

(5) To receive a license as a wholesale distributor-broker under this part, an applicant shall meet the requirements for licensure established by the board by rule under section 17767. The rules must require the applicant to demonstrate to the satisfaction of the board that, at the time of the application for initial licensure, the applicant facilitates deliveries or trades for at least 2,000 qualified pharmacies that are each licensed in good standing in their state of licensure. If the number of qualified pharmacies described in this subsection with which a wholesale distributor-broker facilitates deliveries and trades falls below 2,000, the wholesale distributor-broker may continue to do business in this state. However, a wholesale distributor-broker seeking renewal of its license shall, in addition to meeting any requirements for renewal under section 16201, demonstrate to the satisfaction of the board that the wholesale distributor-broker facilitates deliveries and trades for at least 2,000 qualified pharmacies at the time of license renewal.

(6) A wholesale distributor-broker shall provide a transaction

history, transaction statement, or transaction information to a pharmacy purchasing a drug or device from a pharmacy or qualified pharmacy through the wholesale distributor-broker under this section if any of the following are met:

(a) Federal law requires that the transaction history, transaction statement, or transaction information be provided to the pharmacy.

(b) If the qualified pharmacy provided the transaction history, transaction statement, or transaction information to the wholesale distributor-broker, and the wholesale distributer-broker receives a request for the document from the purchasing pharmacy. A wholesale distributor-broker that receives a document described in this subdivision shall retain it for at least 7 years.

(7) A wholesale distributor-broker that receives notification from a pharmacy or qualified pharmacy that a delivery or trade facilitated by the wholesale distributor-broker involved a drug or device salable on prescription only that is a suspect product or illegitimate product shall notify each of the following within the following time period:

(a) The department, within 5 business days.

(b) The United States Food and Drug Administration, within 10 business days.

(c) Each pharmacy that received the product from the pharmacy or qualified pharmacy, within 5 business days.

(8) Before facilitating the delivery or trade of a drug or device salable on prescription only to a pharmacy, the wholesale distributor-broker shall notify the pharmacy, in writing, that the wholesale distributor-broker will not examine the drug or device for quality or accuracy before the pharmacy receives the drug or

device.

(9) A wholesale distributor-broker shall not facilitate the delivery or trade of a drug or device salable on prescription only between a pharmacy and a qualified pharmacy unless the pharmacy's or qualified pharmacy's license is in good standing in its state of licensure.

(10) A wholesale distributor-broker shall cooperate with the department if the department is investigating a transaction involving the wholesale distributor-broker or a qualified pharmacy with which the wholesale distributor-broker facilitates transactions.

(11) As used in this section:

(a) "Illegitimate product" means that term as defined in 21 USC 360eee.

(b) "Out-of-state pharmacy" means a facility or part of a facility that is located outside of this state and that dispenses prescription drugs or prepares prescription drugs for delivery or distribution under the laws of the state in which it is located.

(c) "Qualified pharmacy" means an out-of-state pharmacy that meets the requirements described in subsection (1).

(d) "Suspect product" means that term as defined in 21 USC 360eee.

(e) "Transaction history" means that term as defined in 21 USC 360eee.

(f) "Transaction information" means that term as defined in 21 USC 360eee.

(g) "Transaction statement" means that term as defined in 21 USC 360eee.

Sec. 17767. The board may promulgate rules and make

determinations necessary or appropriate to the licensing of pharmacists, drugs, dispensers, manufacturers, ~~and wholesalers~~ **wholesale distributors, and wholesale distributor-brokers** under this part.

Sec. 17768. (1) In a manner consistent with part 161, the disciplinary subcommittee may fine, reprimand, or place on probation a person licensed under this part, may deny, limit, suspend, or revoke a person's license, or may order restitution or community service for a violation of this part or rules promulgated under this part.

(2) In addition to the grounds set forth in subsection (1), and in a manner consistent with part 161, the board may fine, reprimand, or place on probation a person licensed under this part, may deny, limit, suspend, or revoke a license issued under this part, or may order restitution or community service if the board finds that any of the following apply to an applicant; a partner, officer, or member of the board of directors of a pharmacy, manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-broker** licensed under this part; a stockholder of a pharmacy, manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-broker** that is a privately held corporation licensed under this part; or a facility manager for a wholesale distributor **or wholesale distributor-broker** designated under section 17748(2):

(a) The applicant or other person described in this subsection lacks good moral character.

(b) Subject to subsection (3), the applicant or other person described in this subsection has been convicted of a misdemeanor or a felony under a state or federal law relating to a controlled substance or the practice of pharmacy.

(c) The applicant or other person described in this subsection has furnished false or fraudulent material information or has knowingly omitted material information in an application filed under this part.

(d) The applicant or other person described in this subsection has maintained a financial interest in a pharmacy, manufacturer, ~~or~~ wholesale distributor, **or wholesale distributor-broker** that has been denied a license or federal registration, has had its license or federal registration limited, suspended, or revoked, or has been subject to any other criminal, civil, or administrative penalty.

(e) The applicant or other person described in this subsection is not in compliance with article 7 or article 8 or the rules promulgated under article 7 or article 8.

(f) The applicant or other person described in this subsection has violated section 17748.

(3) Except for a conviction for a misdemeanor under section 7404(2)(d) or a local ordinance that is substantially similar to section 7404(2)(d), the reference to a misdemeanor in subsection (2)(b) applies only to a conviction for a misdemeanor that is directly related to the manufacture, delivery, possession, possession with intent to manufacture or deliver, use, distribution, prescription, or dispensing of a controlled substance. Subsection (2)(b) does not apply to a conviction for a misdemeanor based upon an unintentional error or omission involving a clerical or record-keeping function.