SUBSTITUTE FOR

SENATE BILL NO. 630

A bill to amend 1978 PA 368, entitled

"Public health code,"

by amending sections 16111, 16333, 17705, 17706, 17707, 17709, 17722, 17742, 17748, 17767, and 17768 (MCL 333.16111, 333.16333, 333.17705, 333.17706, 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 17706 as amended by 2014 PA 280, sections 17707, 17709, 17722, 17742, 17748, and 17768 as amended by 2020 PA 4, and section 17767 as amended by 1993 PA 79, and by adding sections 17748e and 17748f.

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~~ **75.00**

(*ii*)	Pharmacy.....	~~35.00~~ **75.00**
(*iii*)	Drug control.....	~~20.00~~ **75.00**
(*iv*)	Manufacturer, ~~or wholesaler~~**wholesale distributor, or wholesale distributor-broker**.....	~~50.00~~ **75.00**
(*v*)	Pharmacy technician.....	~~25.00~~ **75.00**
(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. 17706. (1) "Manufacturer" means a person that prepares, produces, derives, propagates, compounds, processes, packages, or repackages a drug or device salable on prescription only, or otherwise changes the container or the labeling of a drug or device salable on prescription only, and that supplies, distributes, sells, offers for sale, barters, or otherwise disposes of that drug or device and any other drug or device salable on prescription only, to another person for resale, compounding, or dispensing. **Manufacturer does not include a pharmacy unless the pharmacy meets the requirements described in section 17748f.**

(2) "Official compendium" means the United States ~~pharmacopoeia~~ **Pharmacopoeia** and the ~~national formulary,~~ **National Formulary**, or the ~~homeopathic pharmacopoeia~~ **Homeopathic Pharmacopoeia** of the United States, as applicable. If an official compendium is revised after ~~the effective date of the amendatory act that added this sentence,~~ **September 30, 2014**, the department shall officially take notice of the revision. Within 30 days after taking notice of the revision, the department, in consultation with the board, shall decide whether the revision continues to protect the public health as it relates to the manner that the official

compendium is used in this act. If the department, in consultation with the board, decides that the revision continues to protect the public health, the department may issue an order to incorporate the revision by reference. If the department issues an order under this subsection to incorporate the revision by reference, the department shall not make any changes to the revision.

(3) "Outsourcing facility" means that term as defined in 21 USC 353b.

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 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, ~~or~~ 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.

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) "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.

(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.

(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.

(7) "Wholesale distributor" means a person, other than a manufacturer ~~, who~~ **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.**

(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. 17722. In addition to the functions set forth in part 161, except as otherwise provided in this part, 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 17742a, 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) Except for a remote pharmacy, a pharmacy shall designate a

pharmacist licensed in this state as the pharmacist in charge for the pharmacy. For a remote pharmacy, the pharmacist designated as the pharmacist in charge of the parent pharmacy shall also serve as the pharmacist in charge of the remote 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 or, if the manufacturer does not hold a license as a pharmacy, 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 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 not more than 3 pharmacies, including remote pharmacies. 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 unless he or she is serving as the PIC of a remote pharmacy. The PIC of a remote pharmacy is not required to be physically present at the remote pharmacy to satisfy the hour requirement described in this subsection, but may satisfy the requirement through the use of a telepharmacy system. The pharmacy and the PIC shall maintain appropriate records and demonstrate compliance with this subsection ~~upon~~ **on** 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 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 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 that is using a wholesale distributor-broker 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 that is using a wholesale distributor-broker, unless all of the following are met:

(a) The pharmacy or qualified pharmacy from which the drug is being obtained receives a request for the drug that identifies the drug's brand name or generic name, lot number, expiration date, quality, quantity, and size.

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

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

(d) The drug is not a controlled substance.

(e) Before delivering or trading the drug, the pharmacy or qualified pharmacy from which the drug is being obtained confirms with the pharmacy or qualified pharmacy receiving the drug that the drug is available for delivery or trade.

(f) The pharmacy or qualified pharmacy from which the drug is being obtained includes with the drug a packaging checklist, confirming that the drug being delivered or traded matches the information identified on the request described in subdivision (a).

(g) The drug is delivered or traded in the original manufacturer's packaging, whether sealed or unsealed, with the drug's national drug code, lot number, and expiration date conspicuously identified on the packaging. 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. However, the pharmacies, or the pharmacy and qualified pharmacy, shall not trade or deliver more than 1 unsealed or partial quantity of the drug during any consecutive 90-day period.

(h) 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 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, regardless of whether the wholesale distributor-broker is subject to disciplinary action under this part, if the wholesale distributor-broker's conduct does not amount to gross negligence as that term is defined in section 7 of 1964 PA 170, MCL 691.1407.

(5) To receive a license as a wholesale distributor-broker under this part, an applicant shall meet the requirements for licensure established by the department in consultation with the board by rule. 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 50 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 50, 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 50 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) A transaction history, transaction statement, or

transaction information is required under the drug supply chain security act, Public Law 113-54.

(b) 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 the document 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 immediately notify each of the following:

(a) The department.

(b) The United States Food and Drug Administration.

(c) Each pharmacy that received the product from the pharmacy or qualified pharmacy.

(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 a delivery or trade of a drug or device salable on prescription only between a pharmacy and a qualified pharmacy unless both of the following are met:

(a) The pharmacy's or qualified pharmacy's license is in good

standing in its state of licensure at the time of the delivery or trade and the wholesale distributor-broker has no knowledge of pending disciplinary action against the pharmacy or qualified pharmacy in its state of licensure.

(b) The wholesale distributor-broker has, for the quarter in which the delivery or trade will occur, received from the pharmacy and qualified pharmacy a signed attestation that the pharmacy or qualified pharmacy holds a license in good standing in its state of licensure and that the pharmacy or qualified pharmacy is in compliance with all applicable federal and state laws. The wholesale distributor-broker shall make an attestation received under this subdivision available to the department on the department's request.

(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. 17748f. (1) A pharmacy shall obtain a license as a wholesale distributor under this part if the total number of dosage units of all prescription drugs distributed by the pharmacy to a person during any consecutive 12-month period is more than 5% of the total number of dosage units of prescription drugs distributed and dispensed by the pharmacy during the same 12-month period.

(2) A pharmacy shall obtain a license as a manufacturer under this part if, during any consecutive 12-month period, the total number of dosage units of all prescription drugs that are prepared or compounded by the pharmacy for the resale, compounding, or dispensing by another person is more than 5% of the total number of dosage units of prescription drugs prepared by the pharmacy during the same 12-month period.

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 manufacturer, ~~or~~ 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 on an unintentional error or omission involving a clerical or record-keeping function.