

PUBLIC HEALTH CODE (EXCERPT)
Act 368 of 1978

333.17748 Pharmacy, manufacturer, wholesale distributor; or wholesale distributor-broker, license required; compounding services; renewal; designation of pharmacist in charge; joint responsibility; exemption; report of change in ownership, management, location, or PIC or facility manager; duties of pharmacist in charge; submission of fingerprints; criminal history check; exception; investigation or inspection of out-of-state applicant or compounding pharmacy; reimbursement for expenses.

Sec. 17748.

(1) Except for a qualified pharmacy as that term is defined in section 17748e, to do business in this state, a pharmacy, manufacturer, 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, 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, wholesale distributor's, or wholesale distributor-broker's compliance with this part and rules promulgated under this part. A person that is a manufacturer, 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 on the request of the board or its designee.

(4) A pharmacy, manufacturer, 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, 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, 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, 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, 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, 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.

History: 1978, Act 368, Eff. Sept. 30, 1978 ;-- Am. 1978, Act 625, Imd. Eff. Jan. 6, 1979 ;-- Am. 1988, Act 462, Eff. Sept. 1, 1989 ;-- Am. 2014, Act 280, Eff. Sept. 30, 2014 ;-- Am. 2014, Act 413, Eff. Mar. 30, 2015 ;-- Am. 2015, Act 169, Eff. Dec. 3, 2015 ;-- Am. 2020, Act 4, Eff. Apr. 26, 2020 ;-- Am. 2020, Act 142, Imd. Eff. July 14, 2020

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