

Act No. 169
Public Acts of 2015
Approved by the Governor
November 3, 2015
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November 3, 2015
EFFECTIVE DATE: December 3, 2015

**STATE OF MICHIGAN
98TH LEGISLATURE
REGULAR SESSION OF 2015**

Introduced by Senator Hune

ENROLLED SENATE BILL No. 195

AN ACT to amend 1978 PA 368, entitled “An act to protect and promote the public health; to codify, revise, consolidate, classify, and add to the laws relating to public health; to provide for the prevention and control of diseases and disabilities; to provide for the classification, administration, regulation, financing, and maintenance of personal, environmental, and other health services and activities; to create or continue, and prescribe the powers and duties of, departments, boards, commissions, councils, committees, task forces, and other agencies; to prescribe the powers and duties of governmental entities and officials; to regulate occupations, facilities, and agencies affecting the public health; to regulate health maintenance organizations and certain third party administrators and insurers; to provide for the imposition of a regulatory fee; to provide for the levy of taxes against certain health facilities or agencies; to promote the efficient and economical delivery of health care services, to provide for the appropriate utilization of health care facilities and services, and to provide for the closure of hospitals or consolidation of hospitals or services; to provide for the collection and use of data and information; to provide for the transfer of property; to provide certain immunity from liability; to regulate and prohibit the sale and offering for sale of drug paraphernalia under certain circumstances; to provide for the implementation of federal law; to provide for penalties and remedies; to provide for sanctions for violations of this act and local ordinances; to provide for an appropriation and supplements; to repeal certain acts and parts of acts; to repeal certain parts of this act; and to repeal certain parts of this act on specific dates,” by amending section 17748 (MCL 333.17748), as amended by 2014 PA 413.

The People of the State of Michigan enact:

Sec. 17748. (1) To do business in this state, a pharmacy, manufacturer, or wholesale distributor, 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 shall designate a pharmacist licensed in or outside of this state as the pharmacist in charge for the wholesale distributor 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. The pharmacy, manufacturer, or wholesale distributor 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 compliance with this part and rules promulgated under this part. A person that is a manufacturer or wholesale distributor 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 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 be submitted with an application for a new pharmacy, manufacturer, or wholesale distributor 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.

(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 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 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 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 be submitted for the individual as required under subsection (6).

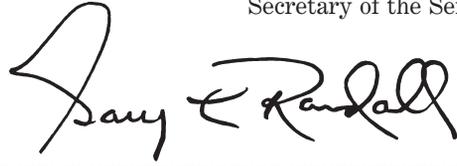
(9) If, as authorized or required under this article, the department inspects or investigates an applicant for a new pharmacy license for a pharmacy that will provide compounding services or a compounding pharmacy, and the applicant or compounding pharmacy is located outside of this state, the applicant 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.

Enacting section 1. This amendatory act takes effect 30 days after the date it is enacted into law.

This act is ordered to take immediate effect.



Secretary of the Senate



Clerk of the House of Representatives

Approved

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Governor