

# SENATE BILL No. 195

March 10, 2015, Introduced by Senator HUNE and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled  
"Public health code,"  
by amending section 17748 (MCL 333.17748), as amended by 2014 PA  
413.

## THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1           Sec. 17748. (1) To do business in this state, a pharmacy,  
2 manufacturer, or wholesale distributor, whether or not located in  
3 this state, must be licensed under this part. To do business in  
4 this state, a person that provides compounding services must be  
5 licensed as a pharmacy or manufacturer under this part and, if a  
6 pharmacy, authorized to provide compounding services under this  
7 section and sections 17748a and 17748b. To do business in this  
8 state, an outsourcing facility must be licensed as a pharmacy under  
9 this part. Licenses are renewable biennially.

1           (2) A pharmacy shall designate a pharmacist licensed in this  
2 state as the pharmacist in charge for the pharmacy. Except as  
3 otherwise provided in this subsection, a manufacturer shall  
4 designate a pharmacist licensed in or outside of this state as the  
5 pharmacist in charge for the manufacturer. Except as otherwise  
6 provided in this subsection, a wholesale distributor shall  
7 designate a pharmacist licensed in or outside of this state as the  
8 pharmacist in charge for the wholesale distributor or shall  
9 designate an employee with the appropriate education or experience,  
10 or both, to assume responsibility for compliance with licensing  
11 requirements as facility manager for the wholesale distributor. The  
12 pharmacy, manufacturer, or wholesale distributor and the individual  
13 designated as the PIC or facility manager under this subsection are  
14 jointly responsible for the pharmacy's, manufacturer's, or  
15 wholesale distributor's compliance with this part and rules  
16 promulgated under this part. A person that is a manufacturer or  
17 wholesale distributor with respect to a device salable on  
18 prescription only but not with respect to any drug salable on  
19 prescription only is exempt from this subsection.

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

26           (4) A pharmacy, manufacturer, or wholesale distributor shall  
27 report to the department a change in ownership, management,

1 location, or its PIC or facility manager designated under  
2 subsection (2) not later than 30 days after the change occurs.

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

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

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

16 (c) Establishment and supervision of the method and manner for  
17 storage and safekeeping of pharmaceuticals, including maintenance  
18 of security provisions to be used when the pharmacy is closed.

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

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

25 ~~—— (6) Except as otherwise provided in this subsection, an~~  
26 ~~applicant for a new pharmacy, manufacturer, or wholesale~~  
27 ~~distributor license under this part who is not a health~~

1 ~~professional licensed or otherwise authorized to engage in a health~~  
2 ~~profession under this article or who is a health professional but~~  
3 ~~was licensed or otherwise authorized to engage in his or her health~~  
4 ~~profession under this article before October 1, 2008 shall submit~~  
5 ~~fingerprints in the same manner as required in section 16174 for~~  
6 ~~the purpose of a criminal history check. The board, department, and~~  
7 ~~department of state police shall comply with section 16174 for the~~  
8 ~~purpose of a criminal history check on an applicant described in~~  
9 ~~this subsection. This subsection does not apply if a criminal~~  
10 ~~history check that meets the requirements of section 16174 was~~  
11 ~~obtained for the applicant within the 2 years preceding the date of~~  
12 ~~the application. To qualify for the exception under this~~  
13 ~~subsection, the applicant shall submit proof of the previous~~  
14 ~~criminal history check with his or her application for a new~~  
15 ~~pharmacy, manufacturer, or wholesale distributor license under this~~  
16 ~~part. If the department or board determines that the criminal~~  
17 ~~history check does not meet the requirements of section 16174 or~~  
18 ~~was not obtained within the time period prescribed, the applicant~~  
19 ~~shall submit fingerprints in the same manner as required in section~~  
20 ~~16174.~~

21 (6) ~~(7)~~—If, as authorized or required under this article, the  
22 department inspects or investigates an applicant for a new pharmacy  
23 license for a pharmacy that will provide compounding services or a  
24 compounding pharmacy, and the applicant or compounding pharmacy is  
25 located outside of this state, the applicant or compounding  
26 pharmacy shall reimburse the department for its expenses incurred  
27 in carrying out its authority or duty to inspect or investigate the

1 applicant or licensee under this article.

2 Enacting section 1. This amendatory act takes effect March 30,

3 2015.