

**HOUSE SUBSTITUTE FOR
SENATE BILL NO. 195**

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

1 state, an outsourcing facility must be licensed as a pharmacy under
2 this part. Licenses are renewable biennially.

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

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

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

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

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

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

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

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

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

27 ~~—— (6) Except as otherwise provided in this subsection, an~~

1 ~~applicant for a new pharmacy, manufacturer, or wholesale~~
2 ~~distributor license under this part who is not a health~~
3 ~~professional licensed or otherwise authorized to engage in a health~~
4 ~~profession under this article or who is a health professional but~~
5 ~~was licensed or otherwise authorized to engage in his or her health~~
6 ~~profession under this article before October 1, 2008 shall submit~~
7 ~~fingerprints in the same manner as required in section 16174 for~~
8 ~~the purpose of a criminal history check. The board, department, and~~
9 ~~department of state police shall comply with section 16174 for the~~
10 ~~purpose of a criminal history check on an applicant described in~~
11 ~~this subsection. This subsection does not apply if a criminal~~
12 ~~history check that meets the requirements of section 16174 was~~
13 ~~obtained for the applicant within the 2 years preceding the date of~~
14 ~~the application. To qualify for the exception under this~~
15 ~~subsection, the applicant shall submit proof of the previous~~
16 ~~criminal history check with his or her application for a new~~
17 ~~pharmacy, manufacturer, or wholesale distributor license under this~~
18 ~~part. If the department or board determines that the criminal~~
19 ~~history check does not meet the requirements of section 16174 or~~
20 ~~was not obtained within the time period prescribed, the applicant~~
21 ~~shall submit fingerprints in the same manner as required in section~~
22 ~~16174.~~

23 (6) EXCEPT AS OTHERWISE PROVIDED IN SUBSECTION (8),
24 FINGERPRINTS FOR THE FOLLOWING INDIVIDUALS SHALL BE SUBMITTED WITH
25 AN APPLICATION FOR A NEW PHARMACY, MANUFACTURER, OR WHOLESALE
26 DISTRIBUTOR LICENSE IN THE SAME MANNER AS REQUIRED IN SECTION 16174
27 FOR THE PURPOSE OF A CRIMINAL HISTORY CHECK:

1 (A) IF THE APPLICATION IS FROM AN INDIVIDUAL, WHO IS NOT A
2 HEALTH PROFESSIONAL LICENSED OR OTHERWISE AUTHORIZED TO ENGAGE IN A
3 HEALTH PROFESSION UNDER THIS ARTICLE OR WHO IS A HEALTH
4 PROFESSIONAL BUT WAS LICENSED OR OTHERWISE AUTHORIZED TO ENGAGE IN
5 HIS OR HER HEALTH PROFESSION UNDER THIS ARTICLE BEFORE OCTOBER 1,
6 2008, FINGERPRINTS FOR THAT INDIVIDUAL.

7 (B) IF THE APPLICATION IS FROM A PARTNERSHIP, FINGERPRINTS FOR
8 ALL PARTNERS AND ANY INDIVIDUAL WHO WILL MANAGE THE DAY-TO-DAY
9 OPERATIONS OF THE NEW PHARMACY, MANUFACTURER, OR WHOLESALE
10 DISTRIBUTOR.

11 (C) IF THE APPLICATION IS FROM A PRIVATELY HELD CORPORATION,
12 FINGERPRINTS FOR ANY INDIVIDUAL WHO WILL MANAGE THE DAY-TO-DAY
13 OPERATIONS OF THE NEW PHARMACY, MANUFACTURER, OR WHOLESALE
14 DISTRIBUTOR. THIS SUBDIVISION ONLY APPLIES TO A PRIVATELY HELD
15 CORPORATION THAT IN THE AGGREGATE OWNS FEWER THAN 75 PHARMACIES,
16 MANUFACTURERS, OR WHOLESALE DISTRIBUTORS ON THE DATE THE
17 CORPORATION SUBMITS ITS LICENSE APPLICATION.

18 (7) THE BOARD, DEPARTMENT, AND DEPARTMENT OF STATE POLICE
19 SHALL CONDUCT THE CRIMINAL HISTORY CHECK ON THE INDIVIDUALS
20 DESCRIBED IN SUBSECTION (6) IN THE SAME MANNER AS DESCRIBED IN
21 SECTION 16174.

22 (8) SUBSECTION (6) DOES NOT APPLY IF A CRIMINAL HISTORY CHECK
23 THAT MEETS THE REQUIREMENTS OF SECTION 16174 HAS BEEN OBTAINED FOR
24 THE INDIVIDUALS DESCRIBED IN SUBSECTION (6) WITHIN THE 2 YEARS
25 PRECEDING THE DATE OF THE APPLICATION FOR A NEW PHARMACY,
26 MANUFACTURER, OR WHOLESALE DISTRIBUTOR LICENSE UNDER THIS PART. TO
27 QUALIFY FOR THE EXCEPTION UNDER THIS SUBSECTION, AN APPLICANT SHALL

1 SUBMIT PROOF OF THE PREVIOUS CRIMINAL HISTORY CHECK FOR EACH
2 INDIVIDUAL DESCRIBED IN SUBSECTION (6), AS APPLICABLE, WITH THE
3 APPLICATION FOR A NEW PHARMACY, MANUFACTURER, OR WHOLESALE
4 DISTRIBUTOR LICENSE UNDER THIS PART. IF THE DEPARTMENT OR BOARD
5 DETERMINES THAT A CRIMINAL HISTORY CHECK FOR AN INDIVIDUAL
6 DESCRIBED IN SUBSECTION (6) DOES NOT MEET THE REQUIREMENTS OF
7 SECTION 16174 OR WAS NOT OBTAINED WITHIN THE TIME PERIOD
8 PRESCRIBED, FINGERPRINTS SHALL BE SUBMITTED FOR THE INDIVIDUAL AS
9 REQUIRED UNDER SUBSECTION (6).

10 (9) ~~(7)~~—If, as authorized or required under this article, the
11 department inspects or investigates an applicant for a new pharmacy
12 license for a pharmacy that will provide compounding services or a
13 compounding pharmacy, and the applicant or compounding pharmacy is
14 located outside of this state, the applicant or compounding
15 pharmacy shall reimburse the department for its expenses incurred
16 in carrying out its authority or duty to inspect or investigate the
17 applicant or licensee under this article.

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