

HOUSE BILL No. 5436

January 27, 2004, Introduced by Reps. Richardville, Woronchak, Stahl, Vander Veen, Taub, Zelenko, Julian, Wojno, Shaffer, Amos, Steil, Mortimer, Howell, Voorhees, Middaugh, Plakas, Kooiman, Robertson, Dennis, Pappageorge, Minore, Hummel, Nofs, Ehardt, Pumford, LaSata, Hager, Garfield, Caul, Stakoe, Woodward, DeRossett, Ruth Johnson, Palmer, Shackleton, Meyer, Koetje, Stewart, Caswell, Nitz, Milosch, Tabor, Farhat, Gaffney, Ward, Hune, Van Regenmorter, Vagnozzi, Spade, O'Neil, Jamnick, Murphy, Moolenaar, Huizenga, Walker and Palsrok and referred to the Committee on Health Policy.

A bill to amend 1978 PA 368, entitled
 "Public health code,"
 by amending sections 17706, 17707, 17722, 17741, and 17763 (MCL 333.17706, 333.17707, 333.17722, 333.17741, and 333.17763),
 section 17706 as amended by 1986 PA 304, section 17707 as amended
 by 1990 PA 333, and section 17763 as amended by 1997 PA 153, and
 by adding sections 17741a and 17744.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 Sec. 17706. (1) "Mail-order pharmacy" means a pharmacy that
 2 receives prescriptions predominantly by mail, fax, or any
 3 electronic means and sells, delivers, or dispenses the
 4 prescription through the mail or other common carrier to
 5 residents of this state.

6 (2) ~~(1)~~ "Manufacturer" means a person who prepares,
 7 produces, derives, propagates, compounds, processes, packages, or

1 repackages a drug or device salable on prescription only, or
2 otherwise changes the container or the labeling of a drug or
3 device salable on prescription only, and who supplies,
4 distributes, sells, offers for sale, barter, or otherwise
5 disposes of that drug or device and any other drug or device
6 salable on prescription only, to another person for resale,
7 compounding, or dispensing.

8 **(3) —(2)—** "Official compendium" means the United States
9 pharmacopoeia and national formulary, homeopathic pharmacopoeia
10 of the United States **revised service**, or a supplement thereof
11 existing on ~~July 1, 1983~~ **the effective date of the amendatory**
12 **act that added section 17741a.**

13 Sec. 17707. (1) "Personal charge" means the immediate
14 physical presence **and supervision** of a pharmacist or dispensing
15 prescriber.

16 (2) "Pharmacist" means an individual licensed under this
17 article to engage in the practice of pharmacy.

18 **(3) "Pharmacist in charge" means a pharmacist who has**
19 **personal charge over a pharmacy and its pharmacists and who**
20 **accepts responsibility for the operation of that pharmacy.**

21 **(4) —(3)—** "Pharmacist intern" or "intern" means an individual
22 who satisfactorily completes the requirements set forth in rules
23 promulgated by the board and is licensed by the board for the
24 purpose of obtaining instruction in the practice of pharmacy from
25 a preceptor approved by the board.

26 **(5) —(4)—** "Pharmacy" means a building or part of a building
27 in which the practice of pharmacy is conducted.

1 (6) ~~(5)~~ "Practice of pharmacy" means a health service, the
2 clinical application of which includes the encouragement of
3 safety and efficacy in the prescribing, dispensing,
4 administering, and use of drugs and related articles for the
5 prevention of illness, and the maintenance and management of
6 health. Professional functions associated with the practice of
7 pharmacy include:

8 (a) The interpretation and evaluation of the prescription.

9 (b) Drug product selection.

10 (c) The compounding, dispensing, safe storage, and
11 distribution of drugs and devices.

12 (d) The maintenance of legally required records.

13 (e) Advising the prescriber and the patient as required as to
14 contents, therapeutic action, utilization, and possible adverse
15 reactions or interactions of drugs.

16 Sec. 17722. In addition to the functions set forth in part
17 161, the board shall:

18 (a) Regulate, control, and inspect the character and standard
19 of pharmacy practice and of drugs and devices manufactured,
20 distributed, prescribed, dispensed, **sold**, administered, or issued
21 in this state and procure samples and limit or prevent the sale
22 of drugs and devices that do not comply with this part.

23 (b) Prescribe minimum criteria for the use of professional
24 and technical equipment and references in the compounding and
25 dispensing of drugs and devices.

26 (c) Grant a pharmacy license for each separate place of
27 practice ~~in which the compounding or dispensing of~~ **that**

1 **compounds or dispenses** prescription drugs or devices, or both, or
2 ~~the receiving of~~ **receives** prescription orders. ~~in this state~~
3 ~~is to be conducted.~~

4 (d) Grant a drug control license for the place of practice of
5 a dispensing prescriber who meets the requirements for the
6 license.

7 (e) Grant a license to a manufacturer or a wholesale
8 distributor of prescription drugs who meets the requirements for
9 the license.

10 (f) Grant a license for each mail-order pharmacy not located
11 in this state that dispenses prescription drugs or devices to
12 residents of this state and meets the requirements for the
13 license.

14 Sec. 17741. (1) A pharmacy shall not ~~be operated~~ **operate**
15 unless licensed by this part. **A mail-order pharmacy that is not**
16 **located in this state shall not sell, deliver, or dispense a**
17 **prescription drug or device to residents of this state unless**
18 **that pharmacy is licensed under this part.**

19 (2) A pharmacy open for business, **including a mail-order**
20 **pharmacy that is not located in this state but required to be**
21 **licensed under this part,** shall ~~be under the personal charge of~~
22 **designate** a pharmacist **in charge**. A pharmacist **in charge** shall
23 not simultaneously ~~have personal charge of~~ **hold that designated**
24 **position at** more than 1 pharmacy. The ~~person to whom a~~ **holder**
25 **of the** pharmacy license ~~is issued~~ and the ~~pharmacists on duty~~
26 **designated pharmacist in charge, if different,** are responsible
27 for compliance with federal and state laws regulating the

1 distribution of drugs and the practice of pharmacy. Pharmacy
2 services shall be conducted under the control and personal charge
3 of a pharmacist **in charge**.

4 (3) A penalty for violation of this part does not affect the
5 pharmacy license of other than the place of business where the
6 violation occurred.

7 **Sec. 17741a. (1) A pharmacist in charge shall do all of the**
8 **following:**

9 (a) **Ensure compliance with federal and state laws and rules**
10 **regulating the distribution of drugs and the practice of pharmacy**
11 **in this state.**

12 (b) **Provide direct control and supervision over all employees**
13 **of the pharmacy who are involved with the procurement, storage,**
14 **compounding, or dispensing of prescription drugs and devices to**
15 **residents of this state.**

16 (c) **Establish policies and procedures for all employees of**
17 **the pharmacy regarding the procurement, storage, compounding, and**
18 **dispensing of prescription drugs and devices to residents of this**
19 **state.**

20 (d) **Establish and implement a record-keeping system for the**
21 **procurement, storage, dispensing, and return of prescription**
22 **drugs and devices for residents of this state.**

23 (e) **Immediately notify the board if he or she ceases to serve**
24 **as the pharmacist in charge.**

25 (f) **Ensure compliance with state and federal rules,**
26 **regulations, and standards for the shipping and handling of**
27 **prescription drugs and devices.**

1 (g) If delivery of the prescription drug or device is through
2 the mail or other common carrier, ensure that the delivery
3 service utilized requires the recipient to provide a signature in
4 order to receive delivery of the prescription drug or device and
5 establish a record-keeping system to maintain those signature
6 records.

7 (h) Establish and implement a record-keeping system to
8 maintain those signature records required under subdivision (g).

9 (2) A pharmacist in charge of a mail-order pharmacy that is
10 not located in this state but required to be licensed under this
11 part shall assume responsibility for each prescription drug or
12 device that is sold, delivered, or dispensed to residents of this
13 state by a pharmacist under his or her personal charge who is not
14 licensed under this part.

15 (3) If a pharmacist in charge is terminated, quits, dies, or
16 otherwise ceases to function in that capacity, the pharmacy shall
17 immediately designate a successor to serve as the pharmacist in
18 charge and notify the board of the termination and new
19 designation.

20 Sec. 17744. (1) A mail-order pharmacy that does not provide
21 to a patient a verbal or face-to-face offer to counsel about a
22 new prescription shall provide the patient with a toll-free
23 telephone service to facilitate direct communication with a
24 licensed pharmacist if the patient has any questions or concerns
25 regarding the prescription drug or device that is received.

26 (2) The board may promulgate rules governing mail-order
27 pharmacies that sell, deliver, or dispense prescription drugs or

1 devices to residents of this state. The rules promulgated under
2 this subsection may include, but are not limited to, regulation
3 of the types of drugs and the quantity of drugs that may be sold,
4 dispensed, or delivered by a mail-order pharmacy.

5 (3) The board may authorize the inspection of mail-order
6 pharmacies from which prescriptions are sold, delivered, or
7 dispensed to residents of this state for compliance with this
8 part and rules promulgated under this part.

9 Sec. 17763. In addition to the grounds set forth in part
10 161, the disciplinary subcommittee may fine, reprimand, or place
11 a pharmacist licensee on probation, or deny, limit, suspend, or
12 revoke the license of a pharmacist or order restitution or
13 community service for a violation or abetting in a violation of
14 this part or rules promulgated under this part, or for 1 or more
15 of the following grounds:

16 ~~(a) Employing the mail to sell, distribute, or deliver a~~
17 ~~drug that requires a prescription when the prescription for the~~
18 ~~drug is received by mail.~~

19 (a) ~~(b)~~ Adulterating, misbranding, or substituting a drug
20 or device knowing or intending that the drug or device shall be
21 used.

22 (b) ~~(c)~~ Permitting the dispensing of prescriptions by an
23 individual who is not a pharmacist, pharmacist intern, or
24 dispensing prescriber.

25 (c) ~~(d)~~ Permitting the dispensing of prescriptions by a
26 pharmacist intern, except in the presence and under the ~~personal~~
27 ~~charge~~ **supervision** of a pharmacist **in charge**.

1 **(d)** ~~-(e)-~~ Selling at auction drugs in bulk or in open
2 packages unless the sale has been approved in accordance with
3 rules of the board.

4 **(e)** ~~-(f)-~~ Promoting a prescription drug to the public in any
5 manner.

6 **(f)** ~~-(g)-~~ In addition to the prohibition contained in
7 section 7405(1)(e), dispensing a prescription for a controlled
8 substance as defined in section 7104 that is written and signed
9 or transmitted by a physician prescriber in a state other than
10 Michigan, unless the prescription is issued by a physician
11 prescriber residing adjacent to the land border between this
12 state and an adjoining state who is authorized under the laws of
13 that state to practice medicine or osteopathic medicine and
14 surgery and to prescribe controlled substances and whose practice
15 may extend into this state, but who does not maintain an office
16 or designate a place to meet patients or receive calls in this
17 state.

18 Enacting section 1. This amendatory act does not take
19 effect unless all of the following bills of the 92nd Legislature
20 are enacted into law:

21 (a) Senate Bill No. _____ or House Bill No. 5438 (request
22 no. 04344'03).

23 (b) Senate Bill No. _____ or House Bill No. 5437 (request
24 no. 04345'03*).

25 (c) Senate Bill No. _____ or House Bill No. 5435 (request
26 no. 05887'03).

27 (d) House Bill No. 4987.