

HOUSE BILL 868

J2

EMERGENCY BILL

3lr2778
CF SB 761

By: **Delegates Murphy, Morhaim, Cullison, Donoghue, Elliott, Hubbard, A. Kelly, Pena-Melnyk, Ready, and ~~V. Turner~~ V. Turner, and Krebs**

Introduced and read first time: February 7, 2013

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 17, 2013

CHAPTER _____

1 AN ACT concerning

2 **Health Occupations – State Board of Pharmacy – Waivers – Pharmacies That**
3 **Only Dispense Devices**

4 FOR the purpose of authorizing the State Board of Pharmacy to waive certain
5 requirements for certain pharmacies that only dispense devices in accordance
6 with certain rules and regulations; making certain technical changes; making
7 this Act an emergency measure; and generally relating to the State Board of
8 Pharmacy and waivers for pharmacies that only dispense devices.

9 BY repealing and reenacting, with amendments,
10 Article – Health Occupations
11 Section 12–403
12 Annotated Code of Maryland
13 (2009 Replacement Volume and 2012 Supplement)

14 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
15 MARYLAND, That the Laws of Maryland read as follows:

16 **Article – Health Occupations**

17 12–403.

18 (a) This section does not require a nonresident pharmacy to violate the laws
19 or regulations of the state in which it is located.

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 (b) Except as otherwise provided in this section, a pharmacy for which a
2 pharmacy permit has been issued under this title:

3 (1) Shall be operated in compliance with the law and with the rules
4 and regulations of the Board;

5 (2) Shall be located and equipped so that the pharmacy may be
6 operated without endangering the public health or safety;

7 (3) Shall ensure that a licensed pharmacist be immediately available
8 on the premises to provide pharmacy services at all times the pharmacy is in
9 operation;

10 (4) Shall be supervised by a licensed pharmacist who is responsible for
11 the operations of the pharmacy at all times the pharmacy is in operation;

12 (5) Shall provide complete pharmaceutical service by preparing and
13 dispensing all prescriptions that reasonably may be expected of a pharmacist;

14 (6) Shall provide services to the general public and may not restrict or
15 limit its services to any group of individuals unless granted a waiver from this
16 requirement by the Board;

17 (7) May not offer pharmaceutical services under any term or condition
18 that tends to interfere with or impair the free and complete exercise of professional
19 pharmaceutical judgment or skill;

20 (8) May not make any agreement that denies a patient a free choice of
21 pharmacist or pharmacy services;

22 (9) May not participate in any activity that is a ground for Board
23 action against a licensed pharmacist under § 12-313 or a registered pharmacy
24 technician under § 12-6B-09 of this title;

25 (10) (i) Shall maintain at all times a current reference library that
26 is appropriate to meet the needs of:

27 1. The practice specialty of that pharmacy; and

28 2. The consumers the pharmacy serves; and

29 (ii) Shall comply with any regulations adopted by the Board
30 establishing the types of texts required to be included in the reference libraries in each
31 of the various practice specialty pharmacies;

1 (11) (i) Shall maintain at all times the minimum professional and
2 technical equipment and sanitary appliances that are necessary in a pharmacy:

3 1. To prepare and dispense prescriptions properly; and

4 2. To otherwise operate a pharmacy; and

5 (ii) Shall:

6 1. Be equipped with the minimum equipment and
7 appliances specified by the Board under this section; and

8 2. Be kept in a clean and orderly manner;

9 (12) Shall store all prescription or nonprescription drugs or devices
10 properly and safely subject to the rules and regulations adopted by the Board;

11 (13) Shall:

12 (i) Make and keep on file for at least 5 years a record of each
13 prescription prepared or dispensed in the pharmacy;

14 (ii) Disclose the records and files maintained of prescriptions for
15 drugs or devices that identify or may be readily associated with the identity of a
16 patient only in accordance with the provisions of Title 4, Subtitle 3 of the Health –
17 General Article; and

18 (iii) Keep additional records as required by the rules and
19 regulations adopted by the Board;

20 (14) Except as otherwise provided under federal law, shall establish
21 and maintain mechanisms to ensure that all prescription drugs or devices used within
22 institutions that provide acute, subacute, or long-term care, or within their related
23 corporate subsidiaries, but stored outside a pharmacy, are stored properly and safely,
24 subject to rules and regulations adopted by the Board and policies established by the
25 institution;

26 (15) Shall provide such personnel, automation, and technology as are
27 necessary to allow the licensed pharmacist employee sufficient time to utilize the
28 pharmacist's knowledge and training and to perform competently the functions of a
29 licensed pharmacist as required by law;

30 (16) Shall provide such personnel, automation, and technology as are
31 necessary to [allow the licensed pharmacist employee or registered pharmacy
32 technician to] comply with the labeling requirements specified in § 12–505 of this title;

1 (17) With regard to a prescription drug that is delivered in this State by
2 the United States mail, a common carrier, or a delivery service and is not personally
3 hand delivered directly to a patient or to the agent of the patient at the residence of
4 the patient or at another location designated by the patient, shall:

5 (i) Provide a general written notice in each shipment of a
6 prescription drug that alerts a consumer that, under certain circumstances, a
7 medication's effectiveness may be affected by exposure to extremes of heat, cold, or
8 humidity; and

9 (ii) Provide a specific written notice in each shipment of a
10 prescription drug that provides a consumer with a toll-free or local consumer access
11 telephone number accessible during regular hours of operation, which is designed to
12 respond to consumer questions pertaining to medications;

13 (18) (i) May maintain a record log of any prescription that is
14 requested to be filled or refilled by a patient in accordance with the provisions of Title
15 4, Subtitle 3 of the Health – General Article;

16 (ii) If the prescription record of a patient includes the patient's
17 Social Security number, shall keep the Social Security number confidential;

18 (iii) May not list in the record log the type of illness, disability, or
19 condition that is the basis of any dispensing or distribution of a drug by a pharmacist;
20 and

21 (iv) May not list a patient's Social Security number, illness,
22 disability, or condition, or the name and type of drug received in the record log if the
23 log is available to other pharmacy customers;

24 (19) May not allow an unauthorized individual to represent that the
25 individual is a pharmacist or registered pharmacy technician;

26 (20) Shall provide information regarding the process for resolving
27 incorrectly filled prescriptions in accordance with existing regulations by:

28 (i) Posting a sign that is conspicuously positioned and readable
29 by consumers at the point where prescription drugs are dispensed to consumers; or

30 (ii) Including written information regarding the process with
31 each prescription dispensed; and

32 (21) Shall dispense or dispose of prescription drugs or medical supplies
33 in accordance with Title 15, Subtitle 6 of the Health – General Article.

1 (c) (1) The Board may waive any of the requirements of this section for
2 the University of Maryland School of Pharmacy, for nuclear pharmacy and dental
3 pharmacy experimental and teaching programs.

4 (2) The Board may waive the requirements of subsection (b)(5) and (6)
5 of this section for pharmacies that are engaged in pharmaceutical specialties which
6 are recognized by the Board under rules and regulations adopted by the Board.

7 **(3) THE BOARD MAY WAIVE THE REQUIREMENTS OF SUBSECTION**
8 **(B)(3) THROUGH (6) AND (15) OF THIS SECTION FOR PHARMACIES THAT ONLY**
9 **DISPENSE DEVICES IN ACCORDANCE WITH RULES AND REGULATIONS ADOPTED**
10 **BY THE BOARD.**

11 **[(3)] (4)** The Board shall waive the requirements of subsection (b)(20)
12 of this section for a pharmacy owned and operated by a hospital, nursing facility, or
13 clinic to which the public does not have access to purchase pharmaceuticals on a retail
14 basis.

15 (d) A nonresident pharmacy shall:

16 (1) Hold a pharmacy permit issued by the Board; and

17 (2) Have a pharmacist on staff who is:

18 (i) Licensed by the Board; and

19 (ii) Designated as the pharmacist responsible for providing
20 pharmaceutical services to patients in the State.

21 (e) (1) In order to obtain a pharmacy permit from the Board, a
22 nonresident pharmacy shall:

23 (i) Submit an application to the Board on the form that the
24 Board requires;

25 (ii) Pay to the Board an application fee set by the Board;

26 (iii) Submit a copy of the most recent inspection report resulting
27 from an inspection conducted by the regulatory or licensing agency of the state in
28 which the nonresident pharmacy is located; and

29 (iv) On the required permit application, identify the name and
30 current address of an agent located in this State officially designated to accept service
31 of process.

32 (2) A nonresident pharmacy shall report a change in the name or
33 address of the resident agent in writing to the Board 30 days prior to the change.

1 (f) Notwithstanding subsection (a) of this section, a nonresident pharmacy
2 shall:

3 (1) Comply with the requirements of subsection (b)(2), (7) through
4 (12), and (19) **OF THIS SECTION** when:

5 (i) Dispensing prescription drugs or prescription devices to a
6 patient in this State; or

7 (ii) Otherwise engaging in the practice of pharmacy in this
8 State;

9 (2) On an annual basis and within 30 days after a change of office,
10 corporate officer, or pharmacist, disclose to the Board the location, names, and titles of
11 all principal corporate officers and all pharmacists who are dispensing prescriptions
12 for drugs or devices to persons in this State;

13 (3) Comply with all lawful directions and requests for information
14 from the regulatory or licensing agency of the state in which it is located and all
15 requests for information made by the Board pursuant to this section;

16 (4) Maintain at all times a valid, unexpired permit to conduct a
17 pharmacy in compliance with the laws of the state in which it is located;

18 (5) Maintain its records of prescription drugs or devices dispensed to
19 patients in this State so that the records are readily retrievable;

20 (6) During its regular hours of operation, but not less than 6 days a
21 week, and for a minimum of 40 hours per week, provide toll-free telephone service to
22 facilitate communication between patients in this State and a pharmacist **OR AN**
23 **INDIVIDUAL** who:

24 (i) Has access to the patient's prescription records; and

25 (ii) Is required to refer patients in the State to the responsible
26 pharmacist licensed in the State, as appropriate;

27 (7) Disclose its toll-free telephone number on a label affixed to each
28 container of drugs or devices;

29 (8) Comply with the laws of this State relating to the confidentiality of
30 prescription records if there are no laws relating to the confidentiality of prescription
31 records in the state in which the nonresident pharmacy is located; and

32 (9) Comply with the requirements of subsection (b)(17) and (20) of this
33 section.

1 (g) Subject to the hearing provisions of § 12-411 of this subtitle, if a
2 pharmacy or a nonresident pharmacy is operated in violation of this section, the Board
3 may suspend the applicable pharmacy permit until the pharmacy complies with this
4 section.

5 (H) THE BOARD MAY WAIVE THE FOLLOWING REQUIREMENTS FOR
6 NONRESIDENT PHARMACIES THAT ONLY DISPENSE DEVICES IN ACCORDANCE
7 WITH RULES AND REGULATIONS ADOPTED BY THE BOARD:

8 (1) SUBSECTIONS (D)(2) AND (F)(6)(II) OF THIS SECTION; AND

9 (2) IF NOT APPLICABLE, SUBSECTIONS (E)(1)(III) AND (F)(4) OF
10 THIS SECTION.

11 SECTION 2. AND BE IT FURTHER ENACTED, That this Act is an emergency
12 measure, is necessary for the immediate preservation of the public health or safety,
13 has been passed by a yea and nay vote supported by three-fifths of all the members
14 elected to each of the two Houses of the General Assembly, and shall take effect from
15 the date it is enacted.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.