

# SENATE BILL 761

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EMERGENCY BILL

3lr2688  
CF HB 868

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By: **Senator Montgomery**

Introduced and read first time: February 1, 2013

Assigned to: Education, Health, and Environmental Affairs

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Committee Report: Favorable

Senate action: Adopted

Read second time: March 11, 2013

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## 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.

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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;

32 (11) (i) Shall maintain at all times the minimum professional and  
33 technical equipment and sanitary appliances that are necessary in a pharmacy;

1                   1.     To prepare and dispense prescriptions properly; and

2                   2.     To otherwise operate a pharmacy; and

3                   (ii)    Shall:

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

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

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

9                   (13)   Shall:

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

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

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

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

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

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

31                  (17)   With regard to a prescription drug that is delivered in this State by  
32     the United States mail, a common carrier, or a delivery service and is not personally

1 hand delivered directly to a patient or to the agent of the patient at the residence of  
2 the patient or at another location designated by the patient, shall:

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

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

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

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

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

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

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

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

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

28 (ii) Including written information regarding the process with  
29 each prescription dispensed; and

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

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

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

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

8           ~~[(3)](4)~~     The Board shall waive the requirements of subsection (b)(20)  
9 of this section for a pharmacy owned and operated by a hospital, nursing facility, or  
10 clinic to which the public does not have access to purchase pharmaceuticals on a retail  
11 basis.

12           (d)     A nonresident pharmacy shall:

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

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

15                           (i)     Licensed by the Board; and

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

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

20                           (i)     Submit an application to the Board on the form that the  
21 Board requires;

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

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

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

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

31           (f)     Notwithstanding subsection (a) of this section, a nonresident pharmacy  
32 shall:

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

3 (i) Dispensing prescription drugs or prescription devices to a  
4 patient in this State; or

5 (ii) Otherwise engaging in the practice of pharmacy in this  
6 State;

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

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

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

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

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

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

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

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

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

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

32 (g) Subject to the hearing provisions of § 12-411 of this subtitle, if a  
33 pharmacy or a nonresident pharmacy is operated in violation of this section, the Board

1 may suspend the applicable pharmacy permit until the pharmacy complies with this  
2 section.

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

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

7 **(2) IF NOT APPLICABLE, SUBSECTIONS (E)(1)(III) AND (F)(4) OF**  
8 **THIS SECTION.**

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

Approved:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.