

SENATE BILL 413

J2

4lr2087
CF HB 301

By: **Senator Dyson**

Introduced and read first time: January 24, 2014

Assigned to: Education, Health, and Environmental Affairs

A BILL ENTITLED

1 AN ACT concerning

2 **Health Occupations – Dentists With Permits to Prepare and Dispense Dental**
3 **Products – Exclusion From Maryland Pharmacy Act**

4 FOR the purpose of providing that the Maryland Pharmacy Act does not apply, under
5 certain circumstances, to a licensed dentist who obtains a certain permit from
6 the State Board of Dental Examiners and who personally prepares and
7 dispenses certain products or rinses; providing that certain provisions of law do
8 not apply to a licensed dentist who obtains a certain permit under a certain
9 provision of this Act; and generally relating to the exclusion of licensed dentists
10 from the Maryland Pharmacy Act.

11 BY repealing and reenacting, without amendments,
12 Article – Health Occupations
13 Section 12–102(a)(1) and (3)
14 Annotated Code of Maryland
15 (2009 Replacement Volume and 2013 Supplement)

16 BY adding to
17 Article – Health Occupations
18 Section 12–102(h)
19 Annotated Code of Maryland
20 (2009 Replacement Volume and 2013 Supplement)

21 BY repealing and reenacting, with amendments,
22 Article – Health Occupations
23 Section 12–102(h), (i), and (j), 12–102.1, 12–102.2, and 12–403
24 Annotated Code of Maryland
25 (2009 Replacement Volume and 2013 Supplement)

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

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



Article – Health Occupations

12–102.

(a) (1) In this section the following terms have the meanings indicated.

(3) “Personally preparing and dispensing” means that the licensed dentist, physician, or podiatrist:

(i) Is physically present on the premises where the prescription is filled; and

(ii) Performs a final check of the prescription before it is provided to the patient.

(H) THIS TITLE DOES NOT PROHIBIT A LICENSED DENTIST WHO OBTAINS A PERMIT FROM THE STATE BOARD OF DENTAL EXAMINERS THAT ALLOWS THE LICENSED DENTIST TO DISPENSE ONLY PRESCRIPTION STRENGTH HOME FLUORIDE PRODUCTS, DENTIN/ENAMEL REMINERALIZING PRODUCTS, AND ANTIMICROBIAL RINSE FROM PERSONALLY PREPARING AND DISPENSING THE PRODUCT OR RINSE WHEN:

(1) THE PRODUCT OR RINSE IS DISPENSED TO A PATIENT OF THE LICENSED DENTIST; AND

(2) THE LICENSED DENTIST ENTERS AN APPROPRIATE RECORD IN THE PATIENT’S CHART THAT THE PRODUCT OR RINSE WAS DISPENSED TO THE PATIENT.

[(h)] (I) This title does not limit the right of a general merchant to sell:

(1) Any nonprescription drug or device;

(2) Any commonly used household or domestic remedy; or

(3) Any farm remedy or ingredient for a spraying solution, in bulk or otherwise.

[(i)] (J) The Board of Pharmacy, the Board of Dental Examiners, the Board of Physicians, and the Board of Podiatric Medical Examiners annually shall report to the Division of Drug Control:

(1) The names and addresses of its licensees who are authorized to personally prepare and dispense prescription drugs; and

1 (2) The names and addresses of its licensees who have reported, in
2 accordance with subsection (c)(2)(iv)12 of this section, that they have personally
3 prepared and dispensed prescription drugs within the previous year.

4 **[(j)] (K)** A dentist, physician, or podiatrist who fails to comply with the
5 provisions of this section governing the dispensing of prescription drugs or devices
6 shall:

7 (1) Have the dispensing permit revoked; and

8 (2) Be subject to disciplinary actions by the appropriate licensing
9 board.

10 12-102.1.

11 **(a) THIS SECTION DOES NOT APPLY TO A LICENSED DENTIST WHO**
12 **OBTAINS A PERMIT FROM THE STATE BOARD OF DENTAL EXAMINERS UNDER §**
13 **12-102(H) OF THIS SUBTITLE.**

14 **(B)** The Division of Drug Control shall enter and inspect the office of a
15 dentist, physician, or podiatrist who holds:

16 (1) An initial dispensing permit:

17 (i) Within 6 months after receiving the report required under §
18 12-102(i)(1) of this subtitle; and

19 (ii) At least one more time during the duration of the permit;
20 and

21 (2) A renewed dispensing permit at least two times during the
22 duration of the permit.

23 **[(b)] (C)** The Division of Drug Control promptly shall report the results of
24 the inspections required under subsection **[(a)] (B)** of this section to the respective
25 board of licensure.

26 12-102.2.

27 **(a) THIS SECTION DOES NOT APPLY TO A LICENSED DENTIST WHO**
28 **OBTAINS A PERMIT FROM THE STATE BOARD OF DENTAL EXAMINERS UNDER §**
29 **12-102(H) OF THIS SUBTITLE.**

30 **(B)** The Board of Dental Examiners, the Board of Physicians, and the Board
31 of Podiatric Medical Examiners shall charge a fee to a dentist, physician, or podiatrist
32 who holds a dispensing permit in an amount that will produce funds to approximate

1 but not exceed the documented costs to the Division of Drug Control for inspections of
2 dispensing permit holders.

3 **[(b)] (C)** Revenues collected by the Board of Dental Examiners, the Board of
4 Physicians, and the Board of Podiatric Medical Examiners under this section shall be
5 paid into the General Fund of the State.

6 12-403.

7 **(a) THIS SECTION DOES NOT APPLY TO A LICENSED DENTIST WHO**
8 **OBTAINS A PERMIT FROM THE STATE BOARD OF DENTAL EXAMINERS UNDER §**
9 **12-102(H) OF THIS TITLE.**

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

12 **[(b)] (C)** Except as otherwise provided in this section, a pharmacy for which
13 a pharmacy permit has been issued under this title:

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

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

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

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

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

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

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

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

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

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

6 1. The practice specialty of that pharmacy; and

7 2. The consumers the pharmacy serves; and

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

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

13 1. To prepare and dispense prescriptions properly; and

14 2. To otherwise operate a pharmacy; and

15 (ii) Shall:

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

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

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

21 (13) Shall:

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

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

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

30 (14) Except as otherwise provided under federal law, shall establish
31 and maintain mechanisms to ensure that all prescription drugs or devices used within

1 institutions that provide acute, subacute, or long-term care, or within their related
2 corporate subsidiaries, but stored outside a pharmacy, are stored properly and safely,
3 subject to rules and regulations adopted by the Board and policies established by the
4 institution;

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

9 (16) Shall provide such personnel, automation, and technology as are
10 necessary to comply with the labeling requirements specified in § 12-505 of this title;

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

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

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

23 (18) (i) May maintain a record log of any prescription that is
24 requested to be filled or refilled by a patient in accordance with the provisions of Title
25 4, Subtitle 3 of the Health – General Article;

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

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

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

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

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

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

5 (ii) Including written information regarding the process with
6 each prescription dispensed; and

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

9 **[(c)] (D)** (1) The Board may waive any of the requirements of this section
10 for the University of Maryland School of Pharmacy, for nuclear pharmacy and dental
11 pharmacy experimental and teaching programs.

12 (2) The Board may waive the requirements of subsection **[(b)(5) and**
13 **(6)] (C)(5) AND (6)** of this section for pharmacies that are engaged in pharmaceutical
14 specialties which are recognized by the Board under rules and regulations adopted by
15 the Board.

16 (3) The Board may waive the requirements of subsection **[(b)(3)**
17 **through (6) and (15)] (C)(3) THROUGH (6) AND (15)** of this section for pharmacies
18 that only dispense devices in accordance with rules and regulations adopted by the
19 Board.

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

24 **[(d)] (E)** A nonresident pharmacy shall:

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

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

27 (i) Licensed by the Board; and

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

30 **[(e)] (F)** (1) In order to obtain a pharmacy permit from the Board, a
31 nonresident pharmacy shall:

1 (i) Submit an application to the Board on the form that the
2 Board requires;

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

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

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

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

12 **[(f)] (G)** Notwithstanding subsection **[(a)] (B)** of this section, a nonresident
13 pharmacy shall:

14 (1) Comply with the requirements of subsection **[(b)(2), (7) through**
15 **(12), and (19)] (C)(2), (7) THROUGH (12), AND (19)** of this section when:

16 (i) Dispensing prescription drugs or prescription devices to a
17 patient in this State; or

18 (ii) Otherwise engaging in the practice of pharmacy in this
19 State;

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

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

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

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

31 (6) During its regular hours of operation, but not less than 6 days a
32 week, and for a minimum of 40 hours per week, provide toll-free telephone service to
33 facilitate communication between patients in this State and a pharmacist or an
34 individual who:

- 1 (i) Has access to the patient's prescription records; and
- 2 (ii) Is required to refer patients in the State to the responsible
3 pharmacist licensed in the State, as appropriate;
- 4 (7) Disclose its toll-free telephone number on a label affixed to each
5 container of drugs or devices;
- 6 (8) Comply with the laws of this State relating to the confidentiality of
7 prescription records if there are no laws relating to the confidentiality of prescription
8 records in the state in which the nonresident pharmacy is located; and
- 9 (9) Comply with the requirements of subsection [(b)(17) and (20)]
10 **(C)(17) AND (20)** of this section.

11 **[(g) (H)]** Subject to the hearing provisions of § 12-411 of this subtitle, if a
12 pharmacy or a nonresident pharmacy is operated in violation of this section, the Board
13 may suspend the applicable pharmacy permit until the pharmacy complies with this
14 section.

15 **[(h) (I)]** The Board may waive the following requirements for nonresident
16 pharmacies that only dispense devices in accordance with rules and regulations
17 adopted by the Board:

- 18 (1) Subsections [(d)(2) and (f)(6)(ii)] **(E)(2) AND (G)(6)(II)** of this
19 section; and
- 20 (2) If not applicable, subsections [(e)(1)(iii) and (f)(4)] **(F)(1)(III) AND**
21 **(G)(4)** of this section.

22 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
23 October 1, 2014.