

Chapter 496

(Senate Bill 413)

AN ACT concerning

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

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

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

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

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

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

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.

(c) (1) THIS SUBSECTION DOES NOT APPLY TO A LICENSED DENTIST WHO OBTAINS A PERMIT FROM THE STATE BOARD OF DENTAL EXAMINERS UNDER SUBSECTION (H) OF THIS SECTION.

(2) This title does not prohibit:

[(1)] (I) A licensed veterinarian from personally preparing and dispensing the veterinarian’s prescriptions;

[(2)] (II) A licensed dentist, physician, or podiatrist from personally preparing and dispensing the dentist’s, physician’s, or podiatrist’s prescriptions when:

[(i)] 1. The dentist, physician, or podiatrist:

[1.] A. Has applied to the board of licensure in this State which licensed the dentist, physician, or podiatrist;

[2.] B. Has demonstrated to the satisfaction of that board that the dispensing of prescription drugs or devices by the dentist, physician, or podiatrist is in the public interest;

[3.] C. Has received a written permit from that board to dispense prescription drugs or devices except that a written permit is not required in order to dispense starter dosages or samples without charge; and

[4.] D. Posts a sign conspicuously positioned and readable regarding the process for resolving incorrectly filled prescriptions or includes written information regarding the process with each prescription dispensed;

[(ii)] 2. The person for whom the drugs or devices are prescribed is a patient of the prescribing dentist, physician, or podiatrist;

[(iii)] 3. The dentist, physician, or podiatrist does not have a substantial financial interest in a pharmacy; and

[(iv)] 4. The dentist, physician, or podiatrist:

[1.] A. Complies with the dispensing and labeling requirements of this title;

[2.] B. Records the dispensing of the prescription drug or device on the patient's chart;

[3.] C. Allows the Division of Drug Control to enter and inspect the dentist's, physician's, or podiatrist's office at all reasonable hours and in accordance with § 12-102.1 of this subtitle;

[4.] D. On inspection by the Division of Drug Control, signs and dates an acknowledgment form provided by the Division of Drug Control relating to the requirements of this section;

[5.] E. Except for starter dosages or samples without charge, provides the patient with a written prescription, maintains prescription files in accordance with § 12-403(b)(13) of this title, and maintains a separate file for Schedule II prescriptions;

[6.] F. Does not direct patients to a single pharmacist or pharmacy in accordance with § 12-403(b)(8) of this title;

[7.] G. Does not receive remuneration for referring patients to a pharmacist or pharmacy;

[8.] H. Complies with the child resistant packaging requirements regarding prescription drugs under Title 22, Subtitle 3 of the Health – General Article;

[9.] I. Complies with drug recalls;

[10.] J. Maintains biennial inventories and complies with any other federal and State record-keeping requirements relating to controlled dangerous substances;

[11.] K. Purchases prescription drugs from a pharmacy or wholesale distributor who holds a permit issued by the Board of Pharmacy, as verified by the Board of Pharmacy;

[12.] L. Annually reports to the respective board of licensure whether the dentist, physician, or podiatrist has personally prepared and dispensed prescription drugs within the previous year; and

[13.] M. Completes ten continuing education credits over a 5-year period relating to the preparing and dispensing of prescription drugs, offered by the Accreditation Council for Pharmacy Education (ACPE) or as approved by the Secretary, in consultation with each respective board of licensure, as a condition of permit renewal; or

[(3)] (III) A hospital-based clinic from dispensing prescriptions to its patients.

(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; AND

(3) THE LICENSED DENTIST AFFIXES A LABEL ON THE PRODUCT OR RINSE CONTAINER THAT INCLUDES:

(I) THE NAME OF THE PATIENT; AND

(II) UNLESS ALREADY PRINTED ON THE CONTAINER:

1. THE EXPIRATION DATE OF THE PRODUCT OR RINSE; AND

2. THE INSTRUCTIONS FOR USING THE PRODUCT OR RINSE.

[(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

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

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

(1) Have the dispensing permit revoked; and

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

12-102.1.

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

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

(1) An initial dispensing permit:

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

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

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

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

12-102.2.

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

(B) The Board of Dental Examiners, the Board of Physicians, and the Board of Podiatric Medical Examiners shall charge a fee to a dentist, physician, or podiatrist who holds a dispensing permit in an amount that will produce funds to approximate but not exceed the documented costs to the Division of Drug Control for inspections of dispensing permit holders.

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

12-403.

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

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

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

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

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

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

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

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

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

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

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

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

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

1. The practice specialty of that pharmacy; and
2. The consumers the pharmacy serves; and

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

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

1. To prepare and dispense prescriptions properly; and
2. To otherwise operate a pharmacy; and

(ii) Shall:

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

2. Be kept in a clean and orderly manner;

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

(13) Shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (1) Hold a pharmacy permit issued by the Board; and
- (2) Have a pharmacist on staff who is:
 - (i) Licensed by the Board; and
 - (ii) Designated as the pharmacist responsible for providing pharmaceutical services to patients in the State.

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

- (i) Submit an application to the Board on the form that the Board requires;
- (ii) Pay to the Board an application fee set by the Board;
- (iii) Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the nonresident pharmacy is located; and
- (iv) On the required permit application, identify the name and current address of an agent located in this State officially designated to accept service of process.

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

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

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

- (i) Dispensing prescription drugs or prescription devices to a patient in this State; or
- (ii) Otherwise engaging in the practice of pharmacy in this State;

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

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

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

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

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

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

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

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

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

(9) Comply with the requirements of subsection **[(b)(17) and (20)] (C)(17) AND (20)** of this section.

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

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

(1) Subsections **[(d)(2) and (f)(6)(ii)] (E)(2) AND (G)(6)(II)** of this section; and

(2) If not applicable, subsections **[(e)(1)(iii) and (f)(4)] (F)(1)(III) AND (G)(4)** of this section.

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

Approved by the Governor, May 15, 2014.