HOUSE BILL 1381

J2 0lr3375
CF SB 662

By: **Delegate Rudolph**
Introduced and read first time: February 18, 2010
Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

Prescription Drugs – Controlled Dangerous Substances – Certification of Information on Delivery

FOR the purpose of requiring deliverers of certain prescription drugs and the recipients of those drugs to endorse a certain form; requiring the form to certify certain information; requiring the retention of the form or a certain record in a certain manner and for a certain period that the State Board of Pharmacy requires; requiring the Board to adopt certain regulations; and generally relating to the delivery of prescription drugs that are controlled dangerous substances to patients.

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–403
Annotated Code of Maryland
(2009 Replacement Volume)

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

Article – Health Occupations

12–403.

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

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

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

(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 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 allow the licensed pharmacist employee or registered pharmacy technician 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) WITH REGARD TO A PRESCRIPTION DRUG THAT IS A CONTROLLED DANGEROUS SUBSTANCE, AS DEFINED UNDER § 5–101(F) OF THE CRIMINAL LAW ARTICLE, THAT IS DELIVERED IN THIS STATE BY ANY MEANS 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) REQUIRE THAT THE DELIVERER AND THE PATIENT OR THE AGENT OF THE PATIENT ENDORSE A DELIVERY FORM THAT IS APPROVED BY THE BOARD THAT CERTIFIES THAT:

1. THE PERSON WHO RECEIVES THE DELIVERY CLAIMS TO BE AT LEAST 18 YEARS OLD, AND THE CLAIM IS SUPPORTED BY DOCUMENTARY PROOF;

2. THE DELIVERER EXAMINED THE PERSON'S DOCUMENTARY PROOF; AND

3. THE PERSON IS THE PATIENT OR THE AGENT OF THE PATIENT; AND

(II) RETAIN EACH DELIVERY FORM ENDORSED UNDER ITEM (I) OF THIS PARAGRAPH OR A RECORD OF EACH DELIVERY FORM, IN THE MANNER AND FOR THE PERIOD THAT THE BOARD REQUIRES;

[(18)**] (19)** (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)**] (20)** May not allow an unauthorized individual to represent that the individual is a pharmacist or registered pharmacy technician; and

[(20)**] (21)** 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.

(c) (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) 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 shall waive the requirements of subsection **[**(b)(20)**] (B)(21)** 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) A nonresident pharmacy shall hold a pharmacy permit issued by the Board.

(e) (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) A nonresident pharmacy shall:

(1) Comply with the laws of the state in which it is located;

(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 who has access to the patient's prescription records;

(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)**, (18),** and **[**(20)**] (21)** of this section.

(g) 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) THE BOARD SHALL ADOPT REGULATIONS TO CARRY OUT SUBSECTION (B)(18) OF THIS SECTION.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2010.