

SENATE BILL 132

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2lr0928
CF HB 334

By: **Senator Conway**

Introduced and read first time: January 18, 2012

Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 8, 2012

CHAPTER _____

1 AN ACT concerning

2 **Health Occupations – State Board of Pharmacy – Jurisdiction Over**
3 **Nonresident Pharmacies**

4 FOR the purpose of ~~specifying the laws or regulations that apply to a nonresident~~
5 ~~pharmacy if there is a conflict with the provisions of a certain law of this State~~
6 requiring a nonresident pharmacy to have a pharmacist on staff who is licensed
7 by the State Board of Pharmacy and designated as the pharmacist responsible
8 for providing certain services to certain patients; requiring a nonresident
9 pharmacy to comply with certain ~~laws~~ requirements when dispensing
10 prescription drugs or prescription devices to a patient in this State or otherwise
11 engaging in the practice of pharmacy in this State; requiring that certain
12 toll-free telephone service provided by a nonresident pharmacy facilitate
13 communication between patients in this State and a pharmacist who ~~is licensed~~
14 ~~in this State; repealing a certain requirement relating to confidentiality of~~
15 ~~prescription records~~ is required to refer certain patients to a certain pharmacist;
16 altering the scope of disciplinary actions to which a nonresident pharmacy is
17 subject; repealing certain limitations on the authority of the State Board of
18 Pharmacy to impose certain fines or take certain disciplinary action against a
19 nonresident pharmacy; clarifying the inspection requirements applicable to a
20 pharmacy in this State and a nonresident pharmacy; requiring a nonresident
21 pharmacy to submit a copy of a certain inspection report on application for and
22 renewal of a pharmacy permit in this State; and generally relating to pharmacy
23 permit requirements for nonresident pharmacies.

24 ~~BY repealing~~

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.



~~Article – Health Occupations~~
~~Section 12-403(a)~~
~~Annotated Code of Maryland~~
~~(2009 Replacement Volume and 2011 Supplement)~~

~~BY adding to~~
~~Article – Health Occupations~~
~~Section 12-403(a)~~
~~Annotated Code of Maryland~~
~~(2009 Replacement Volume and 2011 Supplement)~~

BY repealing and reenacting, without amendments,
Article – Health Occupations
Section ~~12-403(d), (e), and (g)~~ 12-403(e) and (g)
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section ~~12-403(f)~~ 12-403(d) and (f), 12-409, and 12-604
Annotated Code of Maryland
(2009 Replacement Volume and 2011 Supplement)

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.]~~

~~(A) IF THE LAWS OR REGULATIONS OF THE STATE IN WHICH A NONRESIDENT PHARMACY IS LOCATED CONFLICT WITH THIS SECTION, THE LAWS OR REGULATIONS OF THE STATE IN WHICH THE NONRESIDENT PHARMACY IS LOCATED SHALL APPLY.~~

(d) A nonresident pharmacy shall ~~hold~~:

(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) (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] ~~SUBJECT TO~~ NOTWITHSTANDING SUBSECTION (A) OF THIS SECTION, A nonresident pharmacy shall:**

(1) Comply with [the laws of the state in which it is located] ~~THIS TITLE~~ **THE REQUIREMENTS OF SUBSECTION (B)(2), (7) THROUGH (12), AND (19) 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 who:

~~(I) IS LICENSED IN THIS STATE; AND~~

~~(II)~~ (I) [has] 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) 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.

12-409.

(a) Subject to the hearing provisions of § 12-411 of this subtitle, the Board may suspend or revoke any pharmacy permit, if the pharmacy:

(1) Is conducted so as to endanger the public health or safety;

(2) Violates any of the standards specified in § 12-403 of this subtitle;
or

(3) Otherwise is not conducted in accordance with the law.

(b) (1) A nonresident pharmacy is subject to the disciplinary actions stated in this ~~subsection~~ SUBTITLE.

(2) The Board may fine a nonresident pharmacy in accordance with § 12–410 of this subtitle or deny, revoke, or suspend the permit of a nonresident pharmacy for any violation of § 12–403(d) through (g) of this subtitle.

[(3) The Board may fine a nonresident pharmacy in accordance with § 12–410 of this subtitle or deny, revoke, or suspend the permit of a nonresident pharmacy for conduct which causes harm or injury to a person in this State only if:

(i) The Board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located; and

(ii) The regulatory or licensing agency fails to initiate an investigation within 45 days of receipt of the referral.

(4) The Board shall accept as the final disposition the decision of the regulatory or licensing agency in the state where the nonresident pharmacy is located if:

(i) The regulatory or licensing agency in the state where the nonresident pharmacy is located initiates an investigation within 45 days of the referral; and

(ii) All relevant information acquired by the regulatory or licensing agency in the state where the nonresident pharmacy is located is provided to the Board within a reasonable period.]

12–604.

(a) The Secretary, the Board, or the agents of either, during business hours, may:

(1) Enter any place where drugs, devices, diagnostics, cosmetics, dentifrices, domestic remedies, or toilet articles are manufactured, packaged, stocked, or offered for sale; and

(2) Inspect the drugs, devices, diagnostics, cosmetics, dentifrices, domestic remedies, and toilet articles there.

(b) (1) [Any] A pharmacy IN THIS STATE issued a permit by the Board and subject to inspection under subsection (a) of this section shall be inspected annually.

(2) A NONRESIDENT PHARMACY:

1 **(I) IS SUBJECT TO INSPECTION UNDER SUBSECTION (A) OF**
2 **THIS SECTION BY THE SECRETARY, THE BOARD, OR THE AGENTS OF EITHER;**
3 **AND**

4 **(II) ON APPLICATION FOR AND RENEWAL OF A PHARMACY**
5 **PERMIT IN THIS STATE, SHALL SUBMIT A COPY OF THE MOST RECENT**
6 **INSPECTION REPORT RESULTING FROM AN INSPECTION CONDUCTED BY THE**
7 **REGULATORY OR LICENSING AGENCY OF THE STATE IN WHICH THE**
8 **NONRESIDENT PHARMACY IS LOCATED.**

9 (c) A person may not hinder an inspection conducted under this section.

10 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
11 October 1, 2012.

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.