$\begin{array}{c} \rm J2 \\ \rm CF~SB~132 \end{array}$

By: Delegates Costa and Kipke

Introduced and read first time: January 30, 2012 Assigned to: Health and Government Operations

A BILL ENTITLED

AN ACT concerning

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Health Occupations – State Board of Pharmacy – Jurisdiction Over 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 comply with certain laws when dispensing 7 prescription drugs or prescription devices to a patient in this State or otherwise 8 engaging in the practice of pharmacy in this State; requiring that certain 9 toll-free telephone service provided by a nonresident pharmacy facilitate communication between patients in this State and a pharmacist who is licensed 10 in this State; repealing a certain requirement relating to confidentiality of 11 12 prescription records; repealing certain limitations on the authority of the State 13 Board of Pharmacy to impose certain fines or take certain disciplinary action against a nonresident pharmacy; clarifying the inspection requirements 14 applicable to a pharmacy in this State and a nonresident pharmacy; requiring a 15 16 nonresident pharmacy to submit a copy of a certain inspection report on 17 application for and renewal of a pharmacy permit in this State; and generally 18 relating to pharmacy permit requirements for nonresident pharmacies.

19 BY repealing

20 Article – Health Occupations

21 Section 12–403(a)

22 Annotated Code of Maryland

23 (2009 Replacement Volume and 2011 Supplement)

24 BY adding to

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Article – Health Occupations

26 Section 12–403(a)

27 Annotated Code of Maryland

28 (2009 Replacement Volume and 2011 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 2 3 4 5	BY repealing and reenacting, without amendments, Article – Health Occupations Section 12–403(d), (e), and (g) Annotated Code of Maryland (2009 Replacement Volume and 2011 Supplement)
6 7 8 9	BY repealing and reenacting, with amendments, Article – Health Occupations Section 12–403(f), 12–409, and 12–604 Annotated Code of Maryland (2009 Replacement Volume and 2011 Supplement)
11 12	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
13	Article - Health Occupations
L 4	12–403.
15 16	[(a) This section does not require a nonresident pharmacy to violate the laws or regulations of the state in which it is located.]
17 18 19 20	(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.
21 22	(d) A nonresident pharmacy shall hold a pharmacy permit issued by the Board.
23 24	(e) (1) In order to obtain a pharmacy permit from the Board, a nonresident pharmacy shall:
25 26	(i) Submit an application to the Board on the form that the Board requires;
27	(ii) Pay to the Board an application fee set by the Board;
28 29 30	(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
31 32 33	(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.

$\frac{1}{2}$	(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.
3 4	(f) [A] SUBJECT TO SUBSECTION (A) OF THIS SECTION, A nonresident pharmacy shall:
5 6	(1) Comply with [the laws of the state in which it is located] THIS TITLE WHEN:
7 8	(I) DISPENSING PRESCRIPTION DRUGS OR PRESCRIPTION DEVICES TO A PATIENT IN THIS STATE; OR
9 10	(II) OTHERWISE ENGAGING IN THE PRACTICE OF PHARMACY IN THIS STATE;
11 12 13 14	(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;
15 16 17	(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;
18 19	(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;
20 21	(5) Maintain its records of prescription drugs or devices dispensed to patients in this State so that the records are readily retrievable;
22 23 24	(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:
25	(I) IS LICENSED IN THIS STATE; AND
26	(II) [has] HAS access to the patient's prescription records; AND
27 28	(7) Disclose its toll–free telephone number on a label affixed to each container of drugs or devices[;
29 30 31	(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

- 1 (9)Comply with the requirements of subsection (b)(17) and (20) of this 2 section]. 3 Subject to the hearing provisions of § 12-411 of this subtitle, if a (g) 4 pharmacy or a nonresident pharmacy is operated in violation of this section, the Board 5 may suspend the applicable pharmacy permit until the pharmacy complies with this 6 section. 7 12-409. 8 (a) Subject to the hearing provisions of § 12–411 of this subtitle, the Board 9 may suspend or revoke any pharmacy permit, if the pharmacy: 10 Is conducted so as to endanger the public health or safety; (1) 11 Violates any of the standards specified in § 12–403 of this subtitle; (2) 12 or 13 (3) Otherwise is not conducted in accordance with the law. 14 (b) (1) A nonresident pharmacy is subject to the disciplinary actions 15 stated in this subsection. 16 The Board may fine a nonresident pharmacy in accordance with § (2)17 12-410 of this subtitle or deny, revoke, or suspend the permit of a nonresident 18 pharmacy for any violation of § 12–403(d) through (g) of this subtitle. 19 (3)The Board may fine a nonresident pharmacy in accordance with § 20 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: 2122The Board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located; and 2324The regulatory or licensing agency fails to initiate an investigation within 45 days of receipt of the referral. 2526 **(4)** The Board shall accept as the final disposition the decision of the 27 regulatory or licensing agency in the state where the nonresident pharmacy is located 28if:
- 29 The regulatory or licensing agency in the state where the (i) 30 nonresident pharmacy is located initiates an investigation within 45 days of the 31 referral; and

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1 2 3	(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.]
4	12–604.
5 6	(a) The Secretary, the Board, or the agents of either, during business hours, may:
7 8 9	(1) Enter any place where drugs, devices, diagnostics, cosmetics, dentifrices, domestic remedies, or toilet articles are manufactured, packaged, stocked, or offered for sale; and
10 11	(2) Inspect the drugs, devices, diagnostics, cosmetics, dentifrices, domestic remedies, and toilet articles there.
12 13 14	(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.
15	(2) A NONRESIDENT PHARMACY:
16 17 18	(I) IS SUBJECT TO INSPECTION UNDER SUBSECTION (A) OF THIS SECTION BY THE SECRETARY, THE BOARD, OR THE AGENTS OF EITHER; AND
19 20 21 22	(II) ON APPLICATION FOR AND RENEWAL OF A PHARMACY PERMIT IN THIS STATE, SHALL SUBMIT A COPY OF THE MOST RECENT INSPECTION REPORT RESULTING FROM AN INSPECTION CONDUCTED BY THE RECHNATORY OF THE STATE IN WHICH THE
22 23	REGULATORY OR LICENSING AGENCY OF THE STATE IN WHICH THE NONRESIDENT PHARMACY IS LOCATED.

- 24 (c) A person may not hinder an inspection conducted under this section.
- SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2012.