BY: Economic and Environmental Affairs Committee

AMENDMENTS TO SENATE BILL NO. 412

(First Reading File Bill)

AMENDMENT NO. 1

On page 1, strike beginning with "authorizing" in line 3 down through "and" in line 7 and substitute "requiring certain pharmacies for which a pharmacy permit has been issued"; strike beginning with "authority" in line 9 down through "and" in line 10; and in line 13, strike "12-602" and substitute "12-403(b) and (f)".

AMENDMENT NO. 2

On pages 1 through 5, strike in their entirety the lines beginning with line 19 on page 1 through line 9 on page 5, inclusive, and substitute:

"<u>12-403.</u>

- (b) 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;
- (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

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(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; [and]
- (16) Shall provide such personnel, automation, and technology as are necessary to allow the licensed pharmacist employee to comply with the labeling requirements specified in

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§ 12-505; AND

(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 WHEN THE DRUG IS NOT PERSONALLY HAND DELIVERED DIRECTLY TO A PATIENT OR THE AGENT OF THE PATIENT, OR AT THE RESIDENCE OF THE PATIENT, OR AT A LOCATION DESIGNATED BY THE PATIENT, SHALL:

(I) PROVIDE A GENERAL WRITTEN NOTICE TO BE PLACED INTO EACH SHIPMENT OF A PRESCRIPTION DRUG, THAT ALERTS THE RECIPIENT 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 TO BE PLACED INTO EACH SHIPMENT OF A PRESCRIPTION DRUG, THAT PROVIDES TO THE RECIPIENT A TOLL-FREE OR LOCAL CONSUMER ACCESS TELEPHONE NUMBER ACCESSIBLE DURING REGULAR HOURS OF OPERATION, THAT IS DESIGNED TO RESPOND TO CONSUMER QUESTIONS PERTAINING TO THE EFFECTIVENESS OF A MEDICATION.

(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 drug 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;

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- (5) Maintain its records of prescription drug 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 drug or devices; [and]
- (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 SUBSECTION (B)(17) OF THIS SECTION.".