

Department of Legislative Services  
Maryland General Assembly  
2014 Session

**FISCAL AND POLICY NOTE**

**Revised**

Senate Bill 852

(Senator Conway)

Education, Health, and Environmental Affairs

Health and Government Operations

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**Health Occupations - Dispensers of Devices and Equipment - Exclusion From the Maryland Pharmacy Act**

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This bill exempts, from the requirements of the Maryland Pharmacy Act, a person who only dispenses (1) prescription devices that do not contain a prescription drug; (2) prescription devices within which the only prescription drug is medical oxygen; (3) durable medical equipment; or (4) prosthetics, orthotics, and related supplies.

The bill takes effect June 1, 2014.

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**Fiscal Summary**

**State Effect:** Special fund revenues and expenditures for the State Board of Pharmacy decrease beginning in FY 2014 due to a reduction in the number of pharmacy permits issued and renewed. The exact amount of such reduction cannot be reliably estimated but is not anticipated to be significant.

**Local Effect:** None.

**Small Business Effect:** Potential meaningful. Pharmacies that only dispense the items specified under the bill benefit from an exemption from regulatory requirements.

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**Analysis**

**Current Law:** The State Board of Pharmacy regulates the distribution and dispensing of prescription drugs and devices. "Prescription device" is defined as any device required by federal law to be dispensed only by a prescription. If a device is a "prescription device," any entity dispensing those devices directly to patients in Maryland is required to have a pharmacy permit or nonresident pharmacy permit from the board. If an entity distributes prescription devices to entities other than patients or consumers

(i.e., pharmacies, ambulatory surgical centers, acute care hospitals) into, out of, or within Maryland, the entity must be licensed as a wholesale distributor in Maryland.

An entity that distributes nonprescription durable medical equipment, as determined by the U.S. Food and Drug Administration, is not required to be licensed by the board but instead must be regulated as a residential service agency by the Office of Health Care Quality.

Generally, a pharmacy must have a pharmacist on staff who is available whenever the pharmacy is open. A nonresident pharmacy must also have a pharmacist on staff who is licensed by the board and designated as the pharmacist responsible for providing pharmaceutical services to patients in Maryland.

Chapter 393 of 2013 authorized the State Board of Pharmacy to waive certain requirements of the Maryland Pharmacy Act for a pharmacy that only dispenses prescription devices. For a pharmacy located in Maryland that only dispenses prescription devices, the board may waive the requirement that a pharmacy must:

- ensure that a licensed pharmacist be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation;
- be supervised by a licensed pharmacist who is responsible for the operations of the pharmacy at all times the pharmacy is in operation;
- provide complete pharmaceutical service by preparing and dispensing all prescriptions that reasonably may be expected of a pharmacist;
- 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; and
- 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.

For a nonresident pharmacy (located outside of Maryland) that only dispenses prescription devices, the board may waive the requirement that a nonresident pharmacy must:

- have a pharmacist on staff who is licensed by the board and designated as the pharmacist responsible for providing pharmaceutical services to patients in Maryland; and
- during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide toll-free telephone service to facilitate communication between patients in Maryland and a pharmacist *or an individual* who has access to the patient's records and is required to refer patients in the State to the responsible pharmacist licensed in the State, as appropriate.

If not applicable, the board may also waive the requirement that a nonresident pharmacy:

- as a condition of obtaining a pharmacy permit from the board, 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
- maintain at all times a valid, unexpired permit to conduct a pharmacy in compliance with the laws of the state in which the nonresident pharmacy is located.

**Background:** Chapter 393 resulted from the Durable Medical Equipment Provider Task Force that the board initiated to address entities that dispense only prescription devices. These entities have sought licensure as pharmacies but have found the expense of having a licensed pharmacist prohibitive. The board noted that there was no real need for a pharmacist since these entities dispense devices such as c-pap machines and diabetic supplies. In lieu of having a pharmacist on staff, the board indicated that it would require, in regulations, that pharmacies that only dispense prescription devices be accredited by a board-approved entity and have other appropriate health care professionals on staff (*i.e.*, respiratory therapists for c-pap companies). In developing these regulations with stakeholders in 2013, the board determined that most of these device-only pharmacies were already accredited by other organizations as a requirement to participate in federal health care programs such as Medicare and Medicaid. Thus, the board determined that these device-only pharmacies may not need to be regulated by the board at all.

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### Additional Information

**Prior Introductions:** None.

**Cross File:** HB 1029 (Delegate Murphy) - Health and Government Operations.

**Information Source(s):** Department of Health and Mental Hygiene, Department of Legislative Services

**Fiscal Note History:** First Reader - February 19, 2014  
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