Department of Legislative Services

Maryland General Assembly
2013 Session

FISCAL AND POLICY NOTE

House Bill 868 (Delegate Murphy, *et al.*)
Health and Government Operations Education, Health, and Environmental Affairs

Health Occupations - State Board of Pharmacy - Waivers - Pharmacies That Only Dispense Devices

This emergency bill authorizes the State Board of Pharmacy to waive certain requirements for pharmacies that only dispense prescription devices in accordance with rules and regulations adopted by the board.

Fiscal Summary

State Effect: Any additional workload on the State Board of Pharmacy can be handled within existing budgeted resources. Revenues are not likely affected.

Local Effect: None.

Small Business Effect: Pharmacies that only dispense devices benefit from reduced regulatory requirements.

Analysis

Bill Summary: 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.

The bill allows all nonresident pharmacies to meet the toll-free telephone service requirement with an individual (rather than just a pharmacist).

Current Law: The State Board of Pharmacy regulates the distribution and dispensing of prescription drugs and devices. The definition of "practice pharmacy" includes prescription devices but does not include any surgical or dental instrument, physical therapy equipment, X-ray apparatus, or component part or accessory of any of those

items. "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.

Entities that distribute nonprescription durable medical equipment, as determined by the federal Food and Drug Administration (FDA), are 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.

Pharmacies 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.

Background: According to the board, the bill is the result of the first Durable Medical Equipment Provider Task Force that the board initiated to address entities that dispense prescription devices but not prescription drugs. These entities have sought licensure as pharmacies but have found the expense of having a licensed pharmacist prohibitive. The board notes that there is 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 indicates that it will require, in regulations, that pharmacies that dispense only 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).

FDA classifies prescription devices based on such factors as the intended use of the device and the risk to the patient or user. There are three classes of devices. Class I devices are those for which general controls are sufficient to provide reasonable assurance of the safety and effectiveness of such devices. Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments. Class II devices are those for which general controls are by themselves insufficient to provide reasonable assurance of the safety and effectiveness of such devices and for which there is sufficient information to establish specific controls on the device. Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes. Class III devices are those for which insufficient information exists to determine that general and specific controls are sufficient to provide reasonable assurance of the safety and effectiveness of such devices and for which premarket approval or premarket notification is required. Examples of Class III devices which require a premarket

approval include replacement heart valves and silicone gel-filled breast implants. Examples of Class III devices which currently require a premarket notification include implantable pacemaker pulse generators.

Additional Information

Prior Introductions: None.

Cross File: SB 761 (Senator Montgomery) - Education, Health, and Environmental Affairs.

Information Source(s): U.S. Food and Drug Administration, Department of Health and Mental Hygiene, Department of Legislative Services

Fiscal Note History: First Reader - February 26, 2013
ncs/ljm

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