

Department of Legislative Services
Maryland General Assembly
2019 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

Senate Bill 916

(Senator Lam)

Education, Health, and Environmental Affairs

Health and Government Operations

Physicians – Dispensing Permit Exemption – Topical Medication

This bill authorizes a licensed physician to dispense a topical medication approved by the U.S. Food and Drug Administration for the treatment of hypotrichosis if the physician complies with specified sections of the Maryland Pharmacy Act and receives a special class of written permit from the Maryland Board of Physicians (MBP).

Fiscal Summary

State Effect: Minimal increase in special fund revenues for MBP beginning in FY 2020. Issuance of the special class of written permit can likely be handled with existing budgeted resources, as discussed below.

Local Effect: None.

Small Business Effect: Potential minimal.

Analysis

Bill Summary: MBP may issue a special class of written permit to a physician if the physician (1) completes one hour of continuing medical education (CME) per year on the dispensing of topical medications developed by a Maryland nonprofit or governmental entity that is accredited by the Accrediting Council for Continuing Medical Education and (2) pays MBP a \$100 permit fee.

If a physician obtains a special written permit from MBP as provided under the bill, the physician does not need to receive a general dispensing permit from MBP or complete

10 hours of CME over a five-year period in order to dispense a topical medication. A physician must otherwise comply with the Maryland Pharmacy Act.

Current Law: Under the Maryland Pharmacy Act, a person must be licensed by the State Board of Pharmacy in order to practice pharmacy in the State, which includes the dispensing of prescription drugs. “Dispensing” means the procedure that results in the receipt of a prescription or nonprescription drug or device by a patient or the patient’s agent and that entails (1) the interpretation of an authorized prescriber’s prescription for a drug or device; (2) the selection and labeling of the drug or device prescribed pursuant to that prescription; and (3) measuring and packaging of the prescribed drug or device in accordance with State and federal laws.

This requirement does not prohibit specified individuals from personally preparing and dispensing prescriptions under specified circumstances, including a licensed physician who (1) has applied to MBP; (2) demonstrated to the satisfaction of MBP that the dispensing of prescription drugs or devices by the physician is in the public interest; (3) has received a written permit from MBP to dispense prescription drugs or devices, with the exception of starter dosages or samples without charge; and (4) posts a sign conspicuously positioned and readable regarding the process for resolving incorrectly filled prescriptions or includes written information regarding the process with each prescription dispensed. The physician also must:

- comply with dispensing and labeling requirements;
- record the dispensing of the prescription drug or device on the patient’s chart;
- allow the Office of Controlled Substances Administration (OCSA) to enter and inspect the physician’s office at all reasonable hours;
- provide the patient with a written prescription and maintain prescription files;
- not direct patients to a single pharmacist or pharmacy;
- not receive remuneration for referring patients to a pharmacist or pharmacy;
- comply with the child resistant packaging requirements regarding prescription drugs;
- comply with drug recalls;
- maintain biennial inventories and comply with any other federal and State recordkeeping requirements relating to controlled dangerous substances;
- purchase prescription drugs from a pharmacy or wholesale distributor who holds a permit issued by the State Board of Pharmacy;
- report annually to MBP whether the physician has personally prepared and dispensed prescription drugs within the previous year; and
- complete 10 hours of CME over a five-year period relating to the preparing and dispensing of prescription drugs.

Chapter 116 of 2016 clarified that a licensed physician may personally prepare and dispense a prescription written by a physician assistant, in accordance with an authorized delegation agreement, or a prescription written by a certified nurse practitioner who works with the physician in the same office setting, if the physician otherwise complies with dispensing requirements.

State Fiscal Effect: The bill creates a special class of written permit that MBP may issue for a \$100 fee. The number of applications for this permit is expected to be minimal; thus, MBP special fund revenues increase minimally beginning in fiscal 2020.

MBP charges \$1,050 for a dispensing permit; of this fee, MBP retains \$50 and the remaining \$1,000 is transferred to OCSA. However, OCSA advises that only a small number of physicians dispense topical products for the treatment of hypotrichosis. Thus, authorizing these physicians to dispense such products with a special class of written permit issued by MBP, rather than a dispensing permit issued by OCSA, does not materially affect revenues for OCSA.

To implement the new special class of written permit, MBP advises that it must hire one full-time licensure analyst associate to adopt regulations, create a new application, review applications, issue the special class of written permits, send out an annual survey, audit the required CME annually, revise delegation agreements, review and approve delegation to physician assistants, review inspection reports, and investigate any compliance issues. The Department of Legislative Services (DLS) disagrees, as discussed below.

Issuance of the special class of written permit will require that MBP adopt regulations, create an application, review applications, and review required dispensing reports received from physicians on an annual basis. However, MBP is already responsible for collecting applications and fees for dispensing permits for physicians. Furthermore, the number of applications for the special class of written permit is expected to be minimal. As such, DLS advises that the bill's requirements can likely be handled within existing resources.

Additional Information

Prior Introductions: HB 1063 of 2018, a similar bill, received a hearing in the House Health and Government Operations Committee but was withdrawn.

Cross File: HB 1288 (Delegate Barron) - Health and Government Operations.

Information Source(s): Maryland Department of Health; Department of Legislative Services

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