

Department of Legislative Services
 Maryland General Assembly
 2022 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 305 (Senator Lam)
 Education, Health, and Environmental Affairs

State Board of Physicians - Dispensing Permits

This bill transfers oversight of the inspection of the offices of physicians who prepare and dispense a prescription drug or device from the Office of Controlled Substances Administration (OCSA) to the State Board of Physicians (MBP). The bill also moves related provisions from the Maryland Pharmacy Act to the Maryland Medical Practice Act. MBP must enter and inspect a physician’s office (1) within six months after issuing an initial dispensing permit and (2) at least once during the duration of a renewed permit. MBP must report any violation related to controlled dangerous substances (CDS) found during the required inspections to OCSA.

Fiscal Summary

State Effect: OCSA general fund revenues decrease by \$97,500 in FY 2023 and \$130,000 annually thereafter; MBP special fund revenues increase accordingly. OCSA general fund expenditures decrease by \$154,500 in FY 2023 to reflect transfer of three positions, as discussed below; MBP special fund expenditures increase accordingly. Future years reflect annualization, increases in ongoing expenses, and reduction of two positions to part-time in FY 2025. To the extent MBP reduces dispensing permit fees, special fund revenues are lower beginning in FY 2025.

(in dollars)	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
GF Revenue	(\$97,500)	(\$130,000)	(\$130,000)	(\$130,000)	(\$130,000)
SF Revenue	\$97,500	\$130,000	-	-	-
GF Expenditure	(\$154,500)	(\$195,400)	(\$201,400)	(\$207,500)	(\$213,800)
SF Expenditure	\$154,500	\$195,400	\$144,800	\$148,900	\$153,200
Net Effect	\$0	\$0	(\$73,400)	(\$71,500)	(\$69,500)

Note:() = decrease; GF = general funds; FF = federal funds; SF = special funds; - = indeterminate increase; (-) = indeterminate decrease

Local Effect: None.

Small Business Effect: Minimal.

Analysis

Bill Summary/Current Law: Under current law, specified individuals are not prohibited 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 bill retains these provisions under the Maryland Medical Practice Act and additionally requires that a physician has an active license in good standing.

Under current law, a physician also must:

- comply with dispensing and labeling requirements;
- record the dispensing of the prescription drug or device on the patient's chart;
- allow 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 CDS;
- 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 continuing medical education (CME) over a five-year period relating to the preparing and dispensing of prescription drugs.

The bill removes the provisions that a physician report annually to MBP on whether the physician has personally prepared and dispensed prescription drugs within the previous year. In addition, the bill removes the requirement regarding the completion of 10 hours of CME and rather specifies that the continuing education requirements for a physician to prepare and dispense prescription drugs will be set by MBP through regulations.

Chapter 535 of 2019 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 MBP. The bill repeals the reference to specified sections of the Maryland Pharmacy Act but retains provisions regarding MBP issuing a topical medication permit.

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. The bill does not change these provisions.

State Fiscal Effect: MBP advises that it charges \$1,050 per physician dispensing permit, of which MBP retains \$50 and forwards the remaining \$1,000 to OCSA to cover the cost of inspections, including three administrative positions. MBP further advises that there are currently 651 active physician dispensing permits, which are renewed every five years; however, the number of active dispensing permits has decreased for the past two years. Under the bill, MBP advises that it would no longer forward dispensing permit fees to OCSA, and the three administrative positions at OCSA associated with inspection of physician offices would transfer to MBP.

While OCSA averaged 468 inspections of physician offices per year from 2014 to 2020, MBP anticipates needing to complete between 300 to 400 inspections per year. MBP estimates it will need to retain the one permanent and two contractual positions from OCSA for the first two years. However, MBP plans to complete the required inspections more efficiently by:

- performing multiple inspections during a single visit when there are multiple physicians with dispensing permits at one location;
- alleviating the need to do a second board inspection following an initial inspection and report from OCSA in preparation for potential disciplinary action;
- reducing the number of unnecessary inspections performed due to OCSA not having updated information from MBP; and
- eliminating the need for OCSA to report any findings from inspections to MBP.

Using these techniques, MBP anticipates being able to reduce the two full-time contractual positions to two part-time (50%) contractual positions beginning in fiscal 2025.

State Revenues: Based on the current dispensing permit fee and number of active physician dispensing permits noted above, and an assumption that one-fifth of the current

active dispensing permits are renewed each year (approximately 130 permits annually), OCSA general fund revenues decrease by \$97,500 in fiscal 2023 (to reflect the bill's October 1, 2022 effective date) and by approximately \$130,000 annually thereafter. MBP special fund revenues increase correspondingly to reflect retaining these revenues.

To the extent that MBP can reduce the cost to complete inspections as planned and is thus able to reduce the physician dispensing permit fee, MBP special fund revenues may be lower beginning in fiscal 2025, commensurate with a reduction in personnel expenditures.

State Expenditures: General fund expenditures for OCSA decrease by an estimated \$154,527 in fiscal 2023, which accounts for the bill's October 1, 2022 effective date. Although not specifically required by the bill, this estimate assumes the transfer of one full-time permanent position and two full-time contractual positions from OCSA to MBP. MBP special fund expenditures increase correspondingly to reflect transfer of the positions.

This estimate does not include any health insurance costs that could be incurred for specified contractual employees under the State's implementation of the federal Patient Protection and Affordable Care Act.

Future year MBP expenditures reflect full salaries with annual increases and employee turnover, annual increases in ongoing operating expenses, and MBP's planned reduction of the two full-time contractual staff to part-time (50%) beginning in fiscal 2025.

Additional Comments: MBP conducted a review of inspection data received from OCSA between October 2014 and March 2020. During this period, MBP received 3,279 inspection reports. Approximately 65% of inspections were of offices in which physicians did not dispense CDS; of those, approximately 56% of reports were returned with no substantive data. From fiscal 2015 through 2020, 3,872 dispensing inspection reports were completed, and approximately 52% identified that the dispensing permit holder "does not dispense, does not dispense here, or does not work here."

Additional Information

Prior Introductions: None.

Designated Cross File: HB 260 (Delegate Carr) - Health and Government Operations.

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

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