

Department of Legislative Services  
 Maryland General Assembly  
 2011 Session

FISCAL AND POLICY NOTE

House Bill 1268 (Delegate Bromwell, *et al.*)  
 Health and Government Operations

Prescription Drugs - Dispensing Permits

This bill requires dentists, physicians, or podiatrists to hold a dispensing permit from the State Board of Pharmacy before dispensing a prescription to a patient. A dispensing permit authorizes the holder to dispense prescription drugs to a patient only when a pharmacy is not “conveniently available” to the patient (within a 10-mile radius of the patient’s home). The bill establishes requirements for initial issuance, renewal, and reinstatement of dispensing permits, as well as disciplinary provisions for permit holders.

Fiscal Summary

**State Effect:** Special fund revenues for the State boards of Dental Examiners, Physicians, and Podiatric Medical Examiners decline beginning in FY 2012 due to transfer of the dispensing permit function to the State Board of Pharmacy. Correspondingly, State Board of Pharmacy special fund revenues increase beginning in FY 2012 from fees for dispensing permits. General fund expenditures for the Department of Health and Mental Hygiene (DHMH) increase by \$137,400 in FY 2012 for additional inspectors in the Division of Drug Control (DDC). Special fund expenditures for the State Board of Pharmacy increase in FY 2012 only to hire contractual staff to assist with the issuance of permits. Future years reflect annualization and inflation.

(in dollars)	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
SF Revenue	-	(-)	(-)	(-)	(-)
GF Expenditure	\$137,400	\$141,500	\$148,400	\$155,800	\$163,500
SF Expenditure	\$31,500	\$0	\$0	\$0	\$0
Net Effect	(\$169,000)	(\$141,500)	(\$148,400)	(\$155,800)	(\$163,500)

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

**Local Effect:** None.

**Small Business Effect:** Minimal.

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## Analysis

**Bill Summary:** A dispensing permit is not transferable and must be issued for a specific location and displayed conspicuously in the office of the permit holder. A permit is valid for five years. To qualify for a dispensing permit, a dentist, physician, or podiatrist must demonstrate that the office for which the application is made will comply with specified standards. An office for which a dispensing permit is issued must:

- be operated in compliance with federal and State laws and State Board of Pharmacy regulations;
- store all prescription drugs properly and safely;
- keep a record of each prescription for at least five years;
- provide for the security of prescription drugs and removal of expired drugs;
- establish safeguards against diversion of prescription drugs;
- comply with repackaging and child resistant packaging restrictions;
- maintain inventories over a two-year period for controlled dangerous substances;
- provide information regarding the process for resolving incorrectly filled prescriptions;
- post a sign that prescription drugs may be purchased from the permit holder if a pharmacy is not “conveniently available” to the patient; and
- comply with an ongoing quality assurance program.

A dentist, physician, or podiatrist who dispenses prescription drugs must:

- be physically present on the premises where the prescription is filled;
- perform a final check of the prescription before it is provided to the patient;
- comply with labeling requirements;
- record the dispensing in the patient’s medical records;
- except for starter dosages or samples dispensed without charge, provide the patient with a written prescription; and
- maintain a single form in the patient’s medical record indicating that a pharmacy is not conveniently available to the patient.

A dentist, physician, or podiatrist may prepare and dispense a starter dose of any drug he or she is authorized to prescribe if he or she holds a dispensing permit from the board, the starter dosage complies with labeling requirements, no charge is made for the starter

dosage (or any charge is incorporated into a flat fee for the office visit), and an appropriate record is entered in the patient's medical record.

The State Board of Pharmacy or its agent may inspect the office of an applicant or permit holder during business hours. The board must notify DDC of the name and address of permit holders. DDC may also enter and inspect a permit holder's office for compliance with federal and State laws and regulations. At the direction of the Secretary of Health and Mental Hygiene, the board, the Chief of Drug Control, or their agents may enter a permit holder's office at any time and investigate with law enforcement officers in accordance with a valid warrant. A person may not hinder such an inspection or investigation.

The State Board of Pharmacy may deny a permit, reprimand a permit holder, place a permit holder on probation, or suspend or revoke a permit. All disciplinary actions are subject to hearing provisions. If the State Board of Pharmacy denies a dispensing permit to an applicant, the board must provide written notice and the reason for denial. A person aggrieved by a final action of the board may not appeal to the Secretary of Health and Mental Hygiene or the board of review, but rather may appeal under the Administrative Procedure Act.

**Current Law:** A licensed dentist, physician, or podiatrist may personally prepare and dispense his or her own prescriptions if the practitioner holds a written dispensing permit from his or her respective licensing board and meets specified criteria, which are largely mirrored by the bill. A dentist, physician, or podiatrist who dispenses prescription drugs may not have a substantial financial interest in a pharmacy, direct patients to a single pharmacist or pharmacy, or receive remuneration for referring patients to a pharmacist or pharmacy.

Under Code of Maryland Regulations (COMAR) 10.13.01, a dispensing permit is valid for five years and subject to a fee of \$50, payable to the respective board. A licensed dentist, physician, or podiatrist must dispense prescription drugs to a patient only when a pharmacy is not conveniently available to the patient. Determination of "conveniently available" must be made by the patient based upon factors to be determined solely at the discretion of the patient. A dentist, physician, or podiatrist must maintain a single form in each patient's chart for each patient to whom prescription drugs are dispensed, which at a minimum, must indicate that a pharmacy is not conveniently available to the patient, state that the determination that a pharmacy is not conveniently available was made solely by the patient, and be signed and dated by the patient before dispensing prescription drugs to the patient for the first time.

Dentists, physicians, or podiatrists who violate these provisions may be subject to discipline by their respective licensing boards.

In addition to these requirements, COMAR 10.09.03 requires a practitioner who dispenses a controlled dangerous substance to have a permit from the U.S. Drug Enforcement Agency and register with DDC. A registration certificate to dispense a controlled dangerous substance costs \$120 and is renewable every two years.

Under COMAR 10.09.03.07, Medicaid only reimburses a licensed physician for dispensing covered drugs to Medicaid recipients if the physician dispenses drugs on a regular basis in the physician's office, the physician's office is not located within a 10-mile radius of a Medicaid participating pharmacy, and Medicaid verifies with the State Board of Pharmacy that the physician is dispensing medication in accordance with accepted pharmacy standards.

**Background:** DDC currently inspects dispensing permit holders. According to the State Board of Pharmacy, DDC inspections have identified that some dispensing permit holders have not been abiding by dispensing laws and regulations. Specifically, not all permit holders are personally preparing or dispensing medications, nor are they following proper recordkeeping, storage, or labeling requirements.

In fiscal 2009, the State Board of Pharmacy submitted proposed regulations (COMAR 10.13.01.02-.04) to implement many of the bill's provisions. The statement of purpose for these regulations indicated that they were intended to enhance patient safety by ensuring that patients receive nonexpired prescription medications that have been stored, packaged, and labeled in accordance with federal and State pharmacy laws; ensure proper patient counseling and review of all medications prescribed for the patient; and limit dispensing by a dentist, physician, or podiatrist unless a pharmacy is not conveniently available to the patient. The regulations have not been published for final adoption.

The State Board of Pharmacy indicates that the bill is intended to centralize issuance of dispensing permits with the board that holds expertise in the practice of pharmacy and authorize the board to enforce the same standards of practice that are expected of pharmacists on other licensed health care providers that dispense prescription drugs. The board notes that the exception in current law that authorizes dentists, physicians, or podiatrists to dispense prescription drugs to patients for whom a pharmacy is not "conveniently available" was initially intended to provide access to prescription drugs in rural areas. However, there are now more dispensing permit holders among the three boards than there are full-service pharmacies in the State.

According to the respective boards, a total of 1,265 dispensing permits are held in Maryland, including approximately 1,170 physicians (State Board of Physicians), 55 dentists (State Board of Dental Examiners), and 40 podiatrists (State Board of Examiners of Podiatrists). There are currently 1,193 full-service retail pharmacies in Maryland.

Three states (Massachusetts, Montana, and Utah) prohibit physician dispensing of prescription drugs. However, most states authorize it with specific restrictions.

- *Virginia* issues two types of licenses to physicians. One type authorizes a physician to practice pharmacy when good cause is shown that pharmacy services are not readily available (generally where there is not a pharmacy within at least 15 to 20 miles). The second and more common type allows a physician to dispense to the physician's own patients, as long as the physician complies with a specific set of regulations and does not delegate the dispensing.
- *New Jersey* limits the quantity of drugs dispensed to a seven-day supply, limits the fee that may be charged for a drug, and requires disclosure to the patient of the availability of the drug from sources outside the practitioner's office. These requirements do not apply if the dispensing office is located 10 or more miles from the nearest pharmacy.
- *Pennsylvania* allows a practitioner (physician, dentist, veterinarian, or other prescriber) to dispense any drugs to the practitioner's own patients after diagnosis or treatment, if the dispensing is done by the actual practitioner.
- *Florida* allows a practitioner who is authorized to prescribe drugs to dispense drugs to the practitioner's own patients in the regular course of practice. The practitioner must comply with all state pharmacy laws and is subject to state inspection for compliance.
- *Georgia* allows a practitioner (physician, dentist, podiatrist, or veterinarian) to dispense to the practitioner's own patients. The practitioner must adhere to the same standards, recordkeeping requirements, and other requirements for the dispensing of drugs applicable to pharmacists.

**State Revenues:** Under current law, fees for dispensing permits accrue to one of the three licensing boards that issue permits. The boards of Physicians and Podiatric Medical Examiners charge \$50 for a permit, while the State Board of Dental Examiners charges \$75. All permits are valid for five years. **Exhibit 1** displays the total number of permits issued by each board and the associated special fund revenues. These figures reflect all permits currently held by licensees of the respective boards and all revenues associated with those permits (not revenues received by the boards in any specific fiscal year).

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**Exhibit 1**  
**Total Dispensing Permits Held in Maryland and Associated Revenues**

<u>Board</u>	<u>Permits</u>	<u>Revenues</u>
Physicians	1,170	\$58,500
Dental Examiners	55	4,125
Podiatric Medical Examiners	40	2,000
<b>Total</b>	1,265	\$64,625

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The bill does not repeal provisions of current law (§ 12-102 of the Health Occupations Article) that require dentists, physicians, and podiatrists to obtain dispensing permits from their respective boards nor does it include any grandfathering provisions for current permit holders. Thus, the bill technically requires practitioners to obtain two permits. However, for purposes of this analysis and based on input from the affected boards, Legislative Services assumes that the permits required from the State Board of Pharmacy, effective October 1, 2011, would supersede the existing permits issued by the other boards.

Thus, special fund revenues decline for the boards of Physicians, Dental Examiners, and Podiatric Medical Examiners beginning in fiscal 2012 as licensees are required to obtain a dispensing permit from the State Board of Pharmacy. The total revenue loss over a five-year period is anticipated to be \$58,500 for the State Board of Physicians, \$4,125 for the State Board of Dental Examiners, and \$2,000 for the State Board of Podiatric Medical Examiners. (Under an alternate scenario, special fund revenues for these boards decline to a lesser extent, if both a permit from the State Board of Pharmacy and the practitioner's licensing board is still required. Even so, given additional restrictions associated with the new permit requirement, fewer practitioners are likely to choose to dispense prescription drugs.)

Conversely, special fund revenues for the State Board of Pharmacy increase by as much as \$45,000 in fiscal 2012 from dispensing permit fees. The board anticipates that approximately 900 individuals (71% of current permit holders) will apply for a dispensing permit from the board in fiscal 2012 at a fee of \$50. Legislative Services notes that it is unclear how many physicians, dentists, and podiatrists will continue to seek dispensing permits given the change in criteria for "conveniently available" from a determination made at the discretion of the patient to a defined standard of whether there is a pharmacy located within a 10-mile radius of the patient's home. Actual revenues for the board will vary based on the number of practitioners that seek permits under this new standard and are likely to be lower than this estimate.

**State Expenditures:** General fund expenditures increase by at least \$137,449 in fiscal 2012, which accounts for the bill's October 1, 2011 effective date. This estimate reflects the cost of hiring two pharmacists by DDC to perform inspections of dispensing permit holders' offices. It includes salaries, fringe benefits, automobile expenses, one-time start-up costs, and ongoing operating expenses. Additional inspectors are needed to determine compliance with enhanced regulation of dispensing permit holders, in particular to verify the availability of pharmacy services within the 10-mile radius of patients' homes. Future year expenditures reflect full salaries with 4.4% annual increases and 3% employee turnover as well as 1% annual increases in ongoing operating expenses.

Special fund expenditures for the State Board of Pharmacy increase by \$31,532 in fiscal 2012 only to hire a short-term contractual office services clerk to assist with data entry and issuance of dispensing permits by the board. This estimate includes a salary and operating expenses for fiscal 2012 only. The board may need additional resources for enforcement in future years based on the actual number of dispensing permits issued.

Special fund expenditures for the other affected boards are not expected to decrease appreciably. Instead, the other boards likely realize operational efficiencies.

	<u><b>FY 2012</b></u>	<u><b>FY 2013</b></u>
<u>General Fund Expenditures</u>		
New Permanent Positions (General Funds)	2	
Permanent Salaries	\$96,637	\$131,471
Vehicle Purchase and Operations	28,767	4,726
One-time Start-up Costs for Permanent Positions	8,130	0
Operating Expenses for Permanent Positions	<u>3,915</u>	<u>5,272</u>
<b>Total General Fund Expenditures</b>	<b>\$137,449</b>	<b>\$141,469</b>
<u>Special Fund Expenses</u>		
New Temporary Contractual Position (Special Funds)	1	-1
Contractual Salary	\$25,239	0
Operating Expenses for Contractual Position	<u>6,293</u>	<u>0</u>
<b>Total Special Fund Expenditures</b>	<b>\$31,532</b>	<b>\$0</b>

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### Additional Information

**Prior Introductions:** None.

**Cross File:** SB 884 (Senator Montgomery) - Education, Health, and Environmental Affairs.

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

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