

Department of Legislative Services
Maryland General Assembly
2012 Session

FISCAL AND POLICY NOTE
Revised

Senate Bill 603

(Senators Montgomery and Conway)

Education, Health, and Environmental Affairs

Health and Government Operations

**Health Care Practitioners - Licensed Dentists, Physicians, and Podiatrists -
Personally Preparing and Dispensing Prescription Drugs and Devices**

This bill requires dentists, physicians, and podiatrists to comply – as a condition of being allowed to personally prepare and dispense prescription drugs – with specified requirements related to dispensing, labeling, inspection, packaging, recall procedure, recordkeeping, purchase, verification, reporting, and continuing education. The bill also requires the boards of Pharmacy, Dental Examiners, Physicians, and Podiatric Medical Examiners to make specified annual reports to the Division of Drug Control (DDC) in the Department of Health and Mental Hygiene (DHMH). In addition, the bill establishes requirements for DDC to (1) inspect the office of a dentist, physician, or podiatrist who holds a dispensing permit; and (2) report the results of the inspections to the respective board of licensure. The boards of Dental Examiners, Physicians, and Podiatric Medical Examiners must charge a fee to the holder of a dispensing permit in an amount that will produce funds (payable to the general funds) to approximate but not exceed DDC’s inspection costs.

The bill takes effect July 1, 2013.

Fiscal Summary

State Effect: General fund expenditures increase by \$234,300 in FY 2014, which reflects the bill’s July 1, 2013 effective date. This estimate reflects the cost of hiring two additional inspectors to conduct the required inspections and one secretary to provide administrative support. The estimate includes salaries, fringe benefits, one-time start-up costs (including automobile purchases), and ongoing operating expenses. Future year expenditures reflect inflation. It is assumed that dispensing permit fees are set in an amount sufficient to approximate DDC’s inspection costs. Consequently, as discussed

below, expenditures are likely exceeded by general fund revenues from the collection of fees beginning in FY 2014.

(in dollars)	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
GF Revenue	-	-	-	-	-
GF Expenditure	\$234,300	\$194,800	\$207,600	\$217,100	\$227,100
Net Effect	-	-	-	-	-

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

Local Effect: None.

Small Business Effect: Potential meaningful impact for small dental, podiatric, and medical practices that must comply with additional recordkeeping, reporting, and continuing education requirements and pay increased fees for dispensing permits.

Analysis

Bill Summary: In addition to existing requirements, as a condition of being allowed to personally prepare and dispense prescription drugs, a dentist, physician, or podiatrist must:

- comply with drug recalls and specified child-resistant packaging requirements;
- 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 that holds a permit issued by the Board of Pharmacy (as verified by the board);
- report annually to the respective board of licensure whether the dentist, physician, or podiatrist has personally prepared and dispensed prescription drugs within the previous year;
- complete, as a condition of permit renewal, 10 continuing education credits (phased in over a five-year period) relating to the preparing and dispensing of prescription drugs, as offered by the Accreditation Council for Pharmacy Education or as approved by the Secretary of Health and Mental Hygiene, in consultation with each respective board of licensure; and
- on inspection by DDC, sign and date an acknowledgement form relating to these and existing requirements.

The boards of Pharmacy, Dental Examiners, Physicians, and Podiatric Medical Examiners are required to report annually to DDC (1) the names and addresses of the board's licensees who are authorized to personally prepare and dispense prescription drugs; and (2) the names and addresses of the board's licensees who have reported, in

accordance with the bill, that they have personally prepared and dispensed prescription drugs within the previous year. DDC must inspect the office of a dentist, physician, or podiatrist who holds an initial dispensing permit within six months of receiving notice of the initial licensure and at least one more time within the duration of the permit. With respect to a holder of a renewal permit, DDC must inspect the office of the holder at least two times within the duration of the permit.

Current Law/Background: A licensed dentist, physician, or podiatrist may personally prepare and dispense his or her own prescriptions if the practitioner (1) holds a written dispensing permit from his or her respective licensing board; (2) meets certain specified criteria; (3) maintains specified records and files and complies with labeling requirements; and (4) does 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. A dentist, physician, or podiatrist who fails to comply with provisions governing the dispensing of prescription drugs or devices must (1) have his or her dispensing permit revoked; and (2) be subject to disciplinary action by the appropriate licensing board. According to the respective boards, a total of 1,265 dispensing permits are held by nonpharmacist practitioners in Maryland, including approximately 1,170 physicians, 55 dentists, and 40 podiatrists.

As specified in regulation, a dispensing permit is valid for five years and subject to a fee of \$50 (or, for dental examiners only, \$75), 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.) The practitioner must maintain a single form in the chart of each patient to whom prescription drugs are dispensed; such a form must, at a minimum, 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 any prescription drugs are dispensed to the patient. Any dentist, physician, or podiatrist who violates these provisions may be subject to discipline by the respective licensing board.

DDC inspects dispensing permit holders. However, although 1,265 dispensing permits were held by practitioners in fiscal 2011, DDC conducted only 301 inspections of dispensing practitioners in that fiscal year.

Senate Bill 884/House Bill 1268 of 2011 would have required dispensing practitioners to hold a dispensing permit from the Board of Pharmacy, but the Senate bill was ultimately referred for interim study by the Senate Education, Health, and Environmental Affairs Committee. That legislation would have also (1) authorized a permit holder to dispense prescription drugs to a patient only when a pharmacy is not “conveniently available”

(i.e., within a 10-mile radius of the patient’s home); and (2) established disciplinary provisions for permit holders and requirements for the initial issuance, renewal, and reinstatement of dispensing permits. Representatives from the boards of Pharmacy, Physicians, Dental Examiners, and Podiatric Medical Examiners met twice in 2011 to discuss these issues and generally agreed upon the provisions reflected in the present bill.

State Fiscal Effect: DDC currently conducts approximately 300 inspections of dispensing permit holders per year. Under the bill, DDC is required to inspect each of these permit holders (of which there are approximately 1,265) twice over a five-year period. Thus, the bill requires DDC to conduct approximately 200 additional inspections per year. Accordingly, DDC advises that additional staff is needed to implement the bill.

DDC conducted almost 1,250 inspections in fiscal 2011 with a staff of five inspectors. If the additional workload were based solely on the bill’s increase in the number of inspections to be conducted by DDC, Legislative Services would advise that only one additional inspector is needed. However, given this increase as well as the bill’s expansion of requirements that inspectors must enforce, Legislative Services concurs with DHMH that two additional inspectors are needed to implement the bill.

Currently, DDC has one office secretary on staff. Legislative Services concurs with DHMH that an additional secretary is needed to implement the bill, given (1) the bill’s increase in the number of inspections (and amount of accompanying paperwork) to be completed by DDC; and (2) the amount of additional reports required by the bill to be submitted to DDC by the relevant health occupations boards.

Therefore, general fund expenditures increase by \$234,309 in fiscal 2014, which reflects the bill’s delayed effective date. This estimate reflects the cost of hiring two additional inspectors to conduct the required inspections and one secretary to provide administrative support. It includes salaries, fringe benefits, automobile purchases and other one-time start-up costs, and ongoing operating expenses.

Positions	3
Salaries and Fringe Benefits	\$181,975
One-time Start-up Costs	15,110
Automobile Purchases	26,994
Ongoing Operating Expenses	<u>10,230</u>
Total FY 2014 State Expenditures	\$234,309

Future year expenditures reflect full salaries with annual increases and employee turnover as well as annual increases in ongoing operating expenses.

The boards of Pharmacy, Dental Examiners, Physicians, and Podiatric Medical Examiners can use existing resources to handle the bill's annual reporting requirements.

It is assumed that dispensing fees are set by the respective boards in an amount sufficient to offset inspection costs to DDC. Thus, expenditures are offset by general fund revenues from the collection of fees beginning in fiscal 2014.

Legislative Services notes that, assuming the number of permit holders remains relatively constant, the fee for a five-year dispensing permit must increase to approximately \$900 in order to offset DDC's *additional* inspection costs under the present bill only. This estimate does not account for DDC's *current* inspection costs, which may include the equivalent of one full- or part-time inspector dedicated to inspecting dispensing permit holders. Legislative Services advises, therefore, that fee revenues collected from permit holders likely must exceed costs under the bill in order to offset DDC's *total* inspection costs associated with dispensing permit holders.

Additional Information

Prior Introductions: None.

Cross File: None.

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

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