

Department of Legislative Services
 Maryland General Assembly
 2013 Session

FISCAL AND POLICY NOTE
 Revised

Senate Bill 166 (Senator Conway)
 Education, Health, and Environmental Affairs

Dentists, Physicians, and Podiatrists - Dispensing Prescription Drugs - Inspection
 by Division of Drug Control

This bill increases the frequency by which the Division of Drug Control (DDC) must inspect the office of a dentist, physician, or podiatrist who holds a dispensing permit. For an initial dispensing permit, in addition to once within six months of initial licensure, DDC must inspect each office at least *annually* rather than at least *one more time* during the duration of the permit. For a renewed dispensing permit, DDC must inspect each office at least *annually* rather than at least *two times* during the duration of the permit.

Fiscal Summary

State Effect: General fund expenditures increase by at least \$197,200 in FY 2014 to hire two additional inspectors to conduct the required inspections and one secretary to provide administrative support. Future years reflect annualization, elimination of one-time-only costs, and inflation. It is assumed that dispensing permit fees will be set in an amount sufficient to approximate DDC’s increased inspection costs. Consequently, expenditures are likely matched by general fund fee revenues beginning in FY 2014.

(in dollars)	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018
GF Revenue	-	-	-	-	-
GF Expenditure	\$197,200	\$214,700	\$224,200	\$234,300	\$244,800
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 may be charged increased fees to cover the cost of the inspections.

Analysis

Current Law: A licensed dentist, physician, or podiatrist may personally prepare and dispense prescription drugs or devices if he or she holds a written dispensing permit from his or her respective licensing board and meets other specified criteria.

Under existing regulations, a dispensing permit is valid for five years and subject to a fee of \$50 (\$75 for dentists), payable to the respective board. In addition to these requirements, a practitioner who dispenses controlled dangerous substances (CDS) must have a permit from the U.S. Drug Enforcement Agency and register with DDC. A registration certificate to dispense CDS costs \$120 and is renewable every two years.

Chapter 267 of 2012 (SB 603), which takes effect July 1, 2013, will require DDC to 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. DDC must promptly report the results of these inspections to the respective licensing boards. Chapter 267 effectively requires DDC to inspect all dispensing permit holders at least twice during the five-year period the permit is valid.

The respective licensing boards must annually report to DDC the names and addresses of all dispensing permit holders and the names and addresses of licensees that have reported that they have personally prepared and dispensed prescriptions within the previous year. Chapter 267 further requires the boards to charge a fee to dispensing permit holders in an amount that will produce funds to approximate, but not exceed, the documented costs to DDC for inspections of permit holders.

A dentist, physician, or podiatrist who dispenses prescription drugs or devices must comply with prescription drug labeling requirements, record the dispensing on a patient's chart, allow DDC to enter and inspect the practitioner's office at all reasonable hours, provide the patient with a written prescription, and maintain prescription files in a specified manner. A dentist, physician, or podiatrist who dispenses 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.

Effective July 1, 2013, a dentist, physician, or podiatrist who dispenses must also (1) comply with drug recalls and child-resistant packaging requirements; (2) maintain biennial inventories and comply with recordkeeping requirements relating to CDS; (3) purchase prescription drugs from a pharmacy or wholesale distributor that holds a permit issued by the State Board of Pharmacy; (4) report annually to the respective board of licensure whether he or she has personally prepared and dispensed prescription drugs

within the previous year; (5) complete 10 continuing education credits as a condition of permit renewal; and (6) on inspection by DDC, sign and date an acknowledgement form relating to these and other requirements.

A pharmacy permit is required to establish or operate a pharmacy in the State. To qualify for a pharmacy permit, pharmacies must arrange for an opening inspection, during which the pharmacy must meet the State Board of Pharmacy's requirements for staffing, equipment, recordkeeping, and prescription dispensing procedures. Once a pharmacy has obtained a permit, the board monitors compliance with these requirements during routine annual inspections.

Background: According to the respective boards, a total of 1,515 dispensing permits are currently held in Maryland, including 1,442 physicians (State Board of Physicians), 52 dentists (State Board of Dental Examiners), and 21 podiatrists (State Board of Examiners of Podiatrists).

DDC, part of the Department of Health and Mental Hygiene's Laboratories Administration, registers 12 types of practitioners and 18 types of establishments to legally manufacture, distribute, dispense, or otherwise handle CDS in Maryland. In fiscal 2012, DDC processed 17,996 CDS permits, conducted 687 CDS and other site inspections, and performed 373 pharmacy inspections. DDC is currently staffed by 10 full-time equivalent positions, including five inspectors. The Governor's proposed fiscal 2014 budget includes funding for three new positions (two inspectors and one office secretary) to support DDC's inspection of dispensing practitioners as required under Chapter 267.

State Fiscal Effects: In fiscal 2012, 114 of the 1,060 inspections conducted by DDC were of dispensing permit holders' offices. However, these inspections were under DDC's CDS enforcement role. Per Chapter 267, beginning in fiscal 2014, DDC will conduct 600 inspections of dispensing permit holder's offices per year (2 inspections per permit holder over a five-year period). Under the bill, DDC would be required to conduct five inspections per dispensing permit holder over a five-year period, rather than the two required under Chapter 267. Thus, the bill requires DDC to conduct an additional 900 inspections per year. Accordingly, DDC advises that additional staff is needed to implement the bill beyond that provided in the Governor's fiscal 2014 proposed budget. The Department of Legislative Services (DLS) concurs.

Therefore, general fund expenditures increase by at least \$197,150 in fiscal 2014, which reflects the bill's October 1, 2013 effective date. This estimate reflects the cost of hiring two additional inspectors to conduct annual inspections and one secretary to provide administrative support, which assumes DDC will be able to achieve efficiencies in its expanded inspection duties. The estimate includes salaries, fringe benefits, automobile purchases and other one-time start-up costs, and ongoing operating expenses.

Positions	3
Salaries and Fringe Benefits	\$142,522
Automobile Purchases	26,994
One-time Start-up Costs	15,480
Ongoing Operating Expenses	<u>12,154</u>
Total FY 2014 State Expenditures	\$197,150

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

It is assumed that, as required by Chapter 267, dispensing permit fees will be 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.

DLS notes that, assuming the number of permit holders remains relatively constant (approximately 1,515 permit holders), the boards will need to collect fee revenues of approximately \$1.08 million to offset inspection costs to DDC over a five-year period under the provisions of Chapter 127 alone (roughly \$713 per permit holder). Additional fee revenues of \$1.1 million would be required to offset the additional DDC inspection costs over a five-year period required by this bill (roughly \$736 per permit holder). Together, these costs equate to a total of \$1,449 per dispensing permit holder (or \$290 per year per permit holder).

Additional Information

Prior Introductions: None.

Cross File: HB 1032 (Delegate Bromwell (By Request)) – Health and Government Operations.

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

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