

**Maryland General Assembly
Department of Legislative Services**

**Proposed Regulations
Department of Health and Mental Hygiene
(DLS Control No. 14-083)**

Overview and Legal and Fiscal Impact

The regulations alter the application, dispensing, inspection, and penalty requirements for licensed physicians, dentists, and podiatrists who apply for or hold permits to dispense prescription drugs.

The regulations do not raise any legal issue of concern.

No additional fiscal impact on State or local agencies beyond that already accounted for in the fiscal and policy note for Chapter 267 of 2012 (SB 603).

Regulations of COMAR Affected

Department of Health and Mental Hygiene:

Drugs: Dispensing of Prescription Drugs by a Licensee: COMAR 10.13.01.02-.06

Legal Analysis

Background

Chapter 267 of 2012 required 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 Act also required 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. In addition, the Act established 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.

Summary of Regulations

The regulations alter the application, dispensing, inspection, and penalty requirements for licensed physicians, dentists, and podiatrists who apply for or hold permits to dispense prescription drugs.

Application Requirements

The regulations require an application for a dispensing permit to include the address of each practice location where the applicant will dispense prescription drugs and an attestation that the applicant will comply with specified dispensing, inspection, statutory, and regulatory requirements. The regulations also require the holder of a dispensing permit to complete ten continuing education credits over a five year period and provide that a permit is non transferable.

Dispensing Requirements

The regulations add the requirements that a licensee who holds a dispensing permit must personally prepare and dispense prescription drugs, comply with specified child resistant packaging requirements and drug recalls, maintain biennial inventories of all stocks of controlled substances, and post conspicuously or include with each prescription the process for resolving incorrectly filled prescriptions. Further, the permit holder must maintain at all times the minimum professional and technical equipment necessary to prepare and dispense prescriptions and is prohibited from making agreements that deny a patient a free choice of pharmacist or pharmacy services.

Inspection Requirements

The regulations establish inspection requirements for holders of dispensing permits. The requirements include:

- the Board of Dental Examiners, the Board of Physicians, and the Board of Podiatric Examiners must provide an annual report to DDC of the names and addresses of licensees who are authorized to prepare and dispense drugs and reported to the appropriate board that they prepared and dispensed drugs in the previous year;
- a licensee must allow DDC to enter and inspect the licensee's practice locations at reasonable hours; and
- DDC must conduct an inspection of a licensee's office:
 - once within six months of the licensee receiving an initial dispensing permit and an additional time within the five year permit period of the initial dispensing permit; and
 - at least two times during the duration of a renewed dispensing permit.

Penalty Requirements

The regulations provide that if a licensee who holds a dispensing permit fails to comply with the requirements governing dispensing of prescription drugs, the appropriate licensing board will revoke the licensee's dispensing permit and subject the licensee to other disciplinary action.

Legal Issue

The regulations do not raise any legal issue of concern.

Statutory Authority and Legislative Intent

The department cites §§ 12-102 and 12-102.1 of the Health Occupations Article as statutory authority for the regulations. Section 12-102 exempts a licensed dentist, physician, or podiatrist who personally prepares and dispenses specified prescriptions from the requirements of Title 12 of the Health Occupations Article, which applies to pharmacists and pharmacies, if the licensed dentist, physician, or podiatrist obtains a dispensing permit from the appropriate health occupations board and meets other specified requirements. Section 12-102.1 requires DDC to conduct specified inspections. Additionally, the department should cite § 12-205(a)(2) of the Health Occupations Article as statutory authority for the regulations. Section 12-205(a)(2) authorizes the State Board of Pharmacy to adopt regulations to carry out the provisions of Title 12 of the Health Occupations Article.

With this addition, the statutory authority is correct and complete. The proposed action complies with legislative intent.

Technical Corrections and Special Notes

Please note that the department has submitted a replacement page for the regulations due to changes it made to Regulation 10.13.01.03 D after submitting the regulations to the Committee. The change requires the continuing education credit requirements to be implemented in accordance with Section 2 of Chapter 267 of 2012, which provides for phasing in the continuing education credit requirements based on the expiration date of a dispensing permit.

Fiscal Analysis

No additional fiscal impact on State or local agencies beyond that already accounted for in the fiscal and policy note for Chapter 267 of 2012 (SB 603).

Agency Estimate of Projected Fiscal Impact

The regulations implement Chapter 267 of 2012, which 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. Chapter 267 also requires DDC to inspect the office of a dispensing permit holder at specified intervals. The department advises that the regulations increase general fund revenues and expenditures by an estimated \$316,000 beginning in fiscal 2014. The Department of Legislative Services disagrees and notes that the fiscal impact of the regulations has already been accounted for in the fiscal and policy note for Chapter 267, which estimated increased general fund expenditures of \$234,300 in fiscal 2014 (and an associated increase in general fund revenues from dispensing fees sufficient to meet or exceed these expenditures).

Impact on Budget

No additional impact on the State operating or capital budget beyond that already accounted for in the fiscal and policy note for Chapter 267. The department indicates that approximately \$220,700 is included in the fiscal 2014 budget for additional DDC expenditures.

Agency Estimate of Projected Small Business Impact

The department advises that the regulations will have minimal or no economic impact on small businesses in the State. The Department of Legislative Services agrees and notes that any impact has already been accounted for in the fiscal and policy note for Chapter 267, which indicated a potential meaningful impact for small dental, podiatric, and medical practices that must comply with additional recordkeeping, reporting, and continuing education requirements, as well as pay increased fees for dispensing permits.

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