

Department of Legislative Services
Maryland General Assembly
2017 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 428 (Senator Klausmeier, *et al.*)
Education, Health, and Environmental Affairs

**State Board of Pharmacy - Dispensing of Drugs Containing Controlled
Dangerous Substances - Requirements**

This bill requires a pharmacist to dispense a drug that contains a substance listed in Schedules II through V in a lockable vial. A pharmacist is not required to comply with this requirement if the patient would have difficulty opening the lockable vial due to physical limitations, and the State Board of Pharmacy may adopt regulations that specify additional exemptions. The board must create and make available to pharmacists a statement that educates patients on the potential for abuse and diversion of drugs that contain substances listed in Schedules II through V.

Fiscal Summary

State Effect: The State Board of Pharmacy can handle the bill's requirements with existing budgeted resources. Revenues are not affected.

Local Effect: None.

Small Business Effect: Meaningful for small business pharmacists who must provide lockable vials for specified prescriptions.

Analysis

Bill Summary: "Lockable vial" means a disposable vial that has "special packaging" (as defined in 15 USC § 1471) and a locking-cap closure mechanism that can be unlocked only by using a numeric or alpha-numeric combination code that is selected by the patient (or guardian) and is encoded in the locking-cap closure mechanism by a pharmacist as part of the process of dispensing the drug.

Current Law: “Special packaging” under 15 USC § 1471 means packaging that is designed or constructed to be significantly difficult for children younger than age five to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but it does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

Controlled dangerous substances (CDS) are listed on one of five schedules (Schedules I through V) set forth in statute based on their potential for abuse and acceptance for medical use.

Chapter 166 of 2011 established the Prescription Drug Monitoring Program (PDMP) to assist with the identification and prevention of prescription drug abuse and the identification and investigation of unlawful prescription drug diversion. PDMP must monitor the prescribing and dispensing of Schedule II through V CDS. When a dispenser (including a pharmacist) fills a prescription for a monitored drug, the dispenser must electronically submit to PDMP identifying information for the patient, prescriber, dispenser, and drug within three business days of dispensing. A dispenser who knowingly fails to submit prescription monitoring data to PDMP is subject to a civil penalty of up to \$500 for each failure to submit required information.

Background: Locking pill bottles are intended to address prescription drug abuse by deterring the theft or misuse of pills from a prescription bottle. Locking pill bottles may also prevent accidental ingestion by children as they are more difficult to open than child safety caps.

In 2015, Illinois established a voluntary, one-year pilot project under which new or refilled prescriptions for a Schedule II controlled substance containing hydrocodone dispensed by a pharmacy must be dispensed in a nonreusable medicine locking closure package. The Illinois Department of Financial and Professional Regulation was authorized to spend up to \$150,000 on the pilot project. The pilot project ended January 1, 2017.

Small Business Effect: The bill requires a pharmacist to dispense Schedules II through V CDS prescriptions in a lockable vial, with specified exceptions. Small business pharmacies will be required to purchase and provide such vials at an estimated cost of \$3.00 to \$5.00 per vial (based on State of Illinois estimates; such vials retail for \$18.00). According to PDMP, nearly 7.0 million CDS prescriptions were dispensed in Maryland annually in 2014 and 2015.

Additional Information

Prior Introductions: None.

Cross File: HB 316 (Delegate Bromwell, *et al.*) - Health and Government Operations.

Information Source(s): Department of Health and Mental Hygiene; *Chicago Tribune*;
Department of Legislative Services

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