

Department of Legislative Services
Maryland General Assembly
2018 Session

FISCAL AND POLICY NOTE
Enrolled

Senate Bill 87

(Chair, Finance Committee)(By Request - Departmental -
Health)

Finance

Health and Government Operations

Controlled Dangerous Substances - Registration, Schedules, Penalties, and
Orders of Impoundment

This departmental bill (1) updates the lists of Schedule I through V controlled dangerous substances (CDS) in statute to reflect federal lists and State exceptions; (2) authorizes the Maryland Department of Health (MDH) to impose a civil penalty for violations of the Controlled Dangerous Substances Act; (3) alters publication requirements for drug and prescription records impoundment notices; and (4) makes other clarifying and technical changes.

Fiscal Summary

State Effect: Potential significant increase in general fund revenues from civil penalties assessed. Minimal decrease in general fund expenditures related to public notices.

Local Effect: None.

Small Business Effect: MDH has determined that this bill has minimal or no impact on small business (attached). The Department of Legislative Services (DLS) concurs with this assessment. (The attached assessment does not reflect amendments to the bill.)

Analysis

Bill Summary: The bill authorizes MDH to impose a civil penalty of up to \$1,000 for each violation of the Maryland Controlled Dangerous Substances Act, which must be remitted to the general fund. MDH must adopt regulations to set penalty standards.

The bill specifies that MDH impoundment notices must be published once a week for two consecutive weeks in a local newspaper.

The bill repeals a “manufacturer’s permit” issued by the State Board of Pharmacy from the definition of a “permit holder” who is subject to MDH impoundment procedures, and instead includes a CDS registration issued by MDH’s Office of Controlled Substances Administration (OCSA) in the definition.

The bill also adds “bulk powders and chemicals” to the types of substances that MDH may impound and makes conforming changes.

Finally, the bill clarifies that a person must be registered with MDH before transporting CDS into the State.

Current Law: CDS are listed on one of five schedules (Schedules I through V) set forth in statute depending on their potential for abuse and acceptance for medical use. Under the federal Controlled Substances Act, for a drug or substance to be classified as Schedule I, the following findings must be made: (1) the substance has a high potential for abuse; (2) the drug or other substance has no currently accepted medical use in the United States; and (3) there is a lack of accepted safety for use of the drug or other substance under medical supervision.

Under the Maryland Controlled Dangerous Substances Act, if the federal government places a substance on Schedules I through V, it is automatically considered a substance on the same schedule under Maryland law unless MDH objects to the designation. MDH must update and republish schedules annually.

A person must be registered by MDH before manufacturing, distributing, or dispensing CDS in the State. An applicant must obtain a separate registration for each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses CDS.

MDH may deny, suspend, revoke, or refuse to renew a registration if MDH finds that the applicant or registrant has (1) materially falsified an application; (2) been convicted of a crime under any federal or state law relating to CDS; (3) had federal registration suspended or revoked and may no longer manufacture, distribute, or dispense a CDS; or (4) otherwise violated State law relating to CDS. MDH may limit revocation or suspension of a registration to the particular CDS for which grounds for revocation or suspension exist.

Pursuant to Chapters 571 and 572 of 2017, MDH may also deny, suspend, revoke, or refuse to renew a registration if the applicant or registrant has surrendered federal registration or has failed to meet the requirements for registration. MDH may also limit an initial

registration or the renewal of a registration to the particular CDS for which grounds for denial or refusal to renew exist.

Except as otherwise specified, MDH may issue an order of impoundment and immediately impound drugs or prescription records of a permit holder or authorized prescriber if (1) a permit holder's permit or authorized prescriber's license has expired or has been revoked or suspended; (2) an application for a permit or license has been denied; (3) a board has determined that the permit holder or authorized prescriber failed to comply with a board order, letter of surrender, or law regarding proper disposition of drugs or records; (4) the drugs pose an imminent threat to public health or safety; or (5) the confidentiality of records is in imminent danger of being compromised.

A "permit holder" means a holder of or applicant for (1) a pharmacy permit, manufacturer's permit, or distributor's permit issued by the State Board of Pharmacy or (2) a dispensing permit issued by a board under the Health Occupations Article.

Before destroying or transferring impounded drugs or records, MDH must publish an impoundment notice *for two consecutive weeks* in a *daily* local newspaper with the date the drugs or records will be destroyed or transferred and specified details as to how the drugs or records may be retrieved.

Background: MDH advises that the bill aligns statute with the U.S. Drug Enforcement Administration's (DEA) schedules of CDS and with the State's designated exceptions. (DEA's list of scheduled CDS and the State's exceptions can be found on [OCSA's website](#).)

MDH also advises that, by specifying that a person must be registered with MDH before transporting CDS into the State, the bill is intended to clarify that both out-of-state CDS distributors who ship CDS *into* the State and CDS distributors who ship CDS *within* the State must obtain proper registration. Further, as the State Board of Pharmacy no longer issues manufacturer's permits, the bill repeals this term from the definition of "permit holder."

MDH further advises that a civil penalty structure for CDS violations allows MDH to institute more appropriate action against CDS registration and permit holders for minor violations (such as recordkeeping issues) that do not necessarily warrant suspension, revocation, or other restrictions against a registration. MDH found 597 violations in fiscal 2016 (including first-time and repeat violations).

Finally, according to MDH, the bill is intended to clarify that bulk powders and chemicals are also subject to impoundment and that MDH must only publish an impoundment notice twice within a 14-day period (rather than daily for 14 consecutive days).

State Revenues: General fund revenues increase, potentially significantly, beginning in fiscal 2019 due to the imposition of civil penalties for violations of the Maryland Controlled Dangerous Substances Act. The extent of any increase depends on the specific civil penalty structure adopted by MDH through regulations and the number of violations found. MDH advises that civil penalties will likely be imposed for repeat violations committed by CDS registrants or permit holders.

Although the bill does not specifically limit MDH's authority to impose civil penalties, this analysis assumes that civil penalties are only assessed against CDS registrants or permit holders. *For illustrative purposes only*, if 50% of the 597 CDS violations found by MDH in fiscal 2016 were for repeat violations, and each of these violations was subject to the maximum \$1,000 civil penalty, general fund revenues could increase by approximately \$223,875 in fiscal 2019 and \$298,500 annually thereafter.

State Expenditures: General fund expenditures for MDH decrease minimally under the bill as a result of less frequent publication of impoundment notices. MDH advises that it currently publishes impoundment notices daily for two consecutive weeks. In fiscal 2017, MDH completed four impoundments; of these, two of the impoundments were completed in conjunction with DEA, and DEA took possession of the impounded drugs and completed the required notices. For the remaining two impoundments, publishing costs totaled approximately \$4,000. MDH estimates that, as the bill requires MDH to publish notices only twice within two consecutive weeks, MDH may realize cost savings; however, MDH is unable to estimate the extent of such savings, as this depends on the number of impoundments per year. DLS advises, however, that any such savings are likely minimal.

Additional Information

Prior Introductions: None.

Cross File: None.

Information Source(s): Judiciary (Administrative Office of the Courts); Maryland Department of Health; Department of Legislative Services

Fiscal Note History: First Reader - January 16, 2018
md/kdm Third Reader - March 16, 2018
Enrolled - April 26, 2018

Analysis by: Sasika Subramaniam

Direct Inquiries to:
(410) 946-5510
(301) 970-5510

ANALYSIS OF ECONOMIC IMPACT ON SMALL BUSINESSES

**Department of Health
Session 2018**

TITLE: **Controlled Dangerous Substances - Schedules,
Registration, Grounds for Sanctions, Show Cause,
and Impoundment Requirements.**

PREPARED BY: Sandra Yankosky

(Program\Unit): Office of Controlled Substances Administration

PART A. ECONOMIC IMPACT RATING

This agency estimates that the proposed bill:

 X WILL HAVE MINIMAL OR NO ECONOMIC IMPACT ON MARYLAND
SMALL BUSINESS

OR

 WILL HAVE MEANINGFUL ECONOMIC IMPACT ON MARYLAND
SMALL BUSINESSES

PART B. ECONOMIC IMPACT ANALYSIS

There is no economic impact on small businesses.