

Department of Legislative Services
Maryland General Assembly
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FISCAL AND POLICY NOTE
First Reader

Senate Bill 469
Finance

(Senator Pinsky, *et al.*)

Drugs and Devices - Electronic Prescriptions - Requirements

This bill requires a health care practitioner authorized by law to prescribe a drug or device to issue a prescription electronically, except under specified exceptions. A violation of the electronic prescription requirement is subject to an administrative fine of \$250 per violation, up to a maximum of \$5,000 in aggregate per calendar year. The Secretary of Health, in consultation with the Maryland Health Care Commission (MHCC), must adopt regulations to establish a waiver from the electronic prescription requirement. A pharmacist may dispense a drug on a written or oral prescription that meets the requirements of the bill. A pharmacist who receives a written or oral prescription is not required to verify that the prescription is an authorized exception to the electronic prescription requirement.

Fiscal Summary

State Effect: General fund revenues increase beginning in FY 2020 from administrative fines issued under the bill. General fund expenditures likely increase to establish a waiver system and enforce the bill, as discussed below.

Local Effect: Health care practitioners in local health departments must comply with the bill's requirements. Revenues are not affected.

Small Business Effect: Potential meaningful.

Analysis

Bill Summary: A health care practitioner may issue a written or oral prescription only if:

- electronic prescribing is not available due to temporary technological or electrical failure;
- the prescription is to be dispensed by a pharmacy located outside the State;
- the prescribing and dispensing entity are the same;
- the prescription includes elements that are not supported by a specified standard;
- the prescription is issued for a drug for which the U.S. Food and Drug Administration requires the prescription to contain certain elements that cannot be transmitted electronically;
- the prescription is not specific to one patient;
- the prescription prescribes a drug under a research protocol;
- the prescription is issued by a health care practitioner who has received a waiver from the Secretary; or
- the prescription is issued under circumstances in which the health care practitioner reasonably determines it would be impractical for the patient and adversely impact the patient's medical condition.

The regulations established by the Secretary must specify that a waiver (1) may not exceed one year and (2) may be granted for economic hardship, technological limitations not reasonably within the health care practitioner's control, or any other exceptional circumstances as demonstrated by the health care practitioner. The Secretary may adopt additional specified regulations.

Current Law: A drug that is intended for use by human beings and is in any of the following classifications may be dispensed by a pharmacist only on a written or oral prescription from a health practitioner authorized by law to prescribe the drug: (1) a habit-forming drug, as specified; (2) a drug that, because of its toxicity or other potentiality for harmful effect, the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a specified health practitioner; and (3) a drug that is limited by an approved application to use under the professional supervision of a specified health practitioner.

A prescription may be written or oral. However, a pharmacist may not dispense a drug on an oral prescription unless the pharmacist promptly writes out and files the prescription.

A prescription for a controlled dangerous substance (CDS) may not be written on a preprinted prescription form that states the name, quantity, or strength of the CDS. When a prescription is written, a separate prescription form is required for each CDS. If a

pharmacist is otherwise satisfied that a prescription is valid, the pharmacist may fill the prescription if the pharmacist promptly writes out and files a prescription for each substance and also files the original prescription. A prescription must be legible.

A pharmacist may not refill and dispense a prescription unless the refilling is authorized by the health practitioner's specification in the original prescription or an oral order of the health practitioner that promptly is written out and filed by the pharmacist.

These prescription requirements do not apply to any drug that is exempted under a rule or regulation adopted by the Secretary.

State Revenues: Under the bill, a violation of the electronic prescription requirement is subject to an administrative fine of \$250 per violation, up to a maximum of \$5,000 in aggregate per calendar year. Thus, general fund revenues increase by an indeterminate amount beginning in fiscal 2020 to the extent fines are imposed and collected.

State Expenditures: The Secretary of Health, in collaboration with MHCC, must adopt regulations to establish a process to issue a waiver to health care practitioners from the bill's electronic prescription requirements. While regulations can be promulgated using existing budgeted resources, general fund expenditures likely increase at least minimally for the Maryland Department of Health (MDH) to establish a waiver system and issue waivers to health care practitioners. Although specific enforcement of the bill is not specified, general fund expenditures likely increase further to the extent MDH enforces the bill's requirements and imposes administrative fines.

Small Business Effect: Small business health care practitioners who do not currently issue electronic prescriptions must comply with the bill's requirements (which may result in additional costs), obtain a waiver from the Secretary (valid only for a year), or be subject to administrative fines totaling up to \$5,000 per year.

Additional Information

Prior Introductions: HB 1416 of 2018 was assigned to the House Health and Government Operations Committee but was withdrawn.

Cross File: HB 409 (Delegate Barron, *et al.*) - Health and Government Operations.

Information Source(s): Maryland Department of Health; Department of Legislative Services

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md/ljm

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