

Department of Legislative Services
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FISCAL AND POLICY NOTE
Third Reader - Revised

Senate Bill 166

(Senator Kelley)

Finance

Health and Government Operations

Drugs and Devices - Electronic Prescriptions - Controlled Dangerous Substances

This bill requires a health practitioner to issue a prescription for a controlled dangerous substance (CDS) electronically, except under specified circumstances. The Secretary of Health, in collaboration with the Maryland Health Care Commission (MHCC), must adopt regulations to establish a waiver of the electronic prescription requirement. The appropriate health occupations board may take disciplinary action against a health practitioner who violates the requirement. A pharmacist may dispense a drug on a written or oral prescription for a CDS that meets the exception requirements, and a pharmacist is not required to verify that the prescription is an authorized exception to the electronic prescription requirement. **The bill takes effect January 1, 2022.**

Fiscal Summary

State Effect: General fund expenditures increase by \$10,000 in FY 2022 for one-time-only costs to establish a database and by an additional indeterminate but likely minimal amount to issue waivers. Revenues are not affected.

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: "Electronic prescription" means a prescription that (1) is generated on an electronic application and transmitted as an electronic data file and (2) if the prescription is for a CDS, complies with federal law.

Exceptions

A health practitioner may issue a written or oral prescription for a CDS 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 prescription is issued by a health practitioner outside the State;
- the health practitioner is prescribing and dispensing the CDS directly to the patient;
- the prescription is being dispensed directly to the patient in accordance with State law;
- the prescription is for an individual who (1) resides in a nursing or assisted living facility; (2) is receiving care through a hospice or palliative care program or at an outpatient renal dialysis facility and the prescription is related to the care provided; or (3) is detained or confined in a correctional facility;
- the prescription is issued by a licensed veterinarian;
- 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 prescribes a drug under a research protocol;
- the prescription is issued by a health practitioner who has received a certain waiver;
- the prescription is issued by a health practitioner who requested a certain waiver that has neither been issued nor been rejected;
- the health practitioner issuing the prescription or the drug for which the prescription is issued falls under a certain waiver;
- the prescription is issued by a health practitioner who writes a low volume of prescriptions for CDS, as determined by MHCC; or
- the prescription is issued by a health practitioner under circumstances in which the health practitioner reasonably determines that it would be impracticable and the delay would adversely impact the patient's medical condition.

Waivers Issued by the Secretary of Health

The Secretary may issue a waiver that applies generally to a group of health practitioners or drugs that meet conditions specified by the Secretary. Any waiver issued for a group of health practitioners must apply to a health practitioner in that group without requiring the health practitioner to apply for a waiver. Otherwise, the regulations adopted must specify that a waiver (1) may not exceed one year and (2) may be granted for economic hardship,

technological limitations that are not reasonably within the control of the health practitioner, or any other exceptional circumstances.

The Secretary may adopt regulations on which temporary technological or electrical failures constitute an exception to the requirement to issue an electronic prescription and the circumstances under which a health practitioner is exempt from the requirement to issue an electronic prescription because the prescription will be dispensed by a pharmacy located outside the State.

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. In general, a person may not dispense a Schedule II CDS without a written prescription from an authorized provider, with specified exceptions.

A prescription for a 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.

Background: Based on data from the Prescription Drug Monitoring Program, there are more than 37,000 health care practitioners in Maryland who can prescribe and more than 5.1 million CDS prescriptions were dispensed in Maryland in 2019.

According to Surescripts, as of June 2019, more than half of all states require the use of electronic prescribing for opioids, CDS, or all prescriptions.

By January 2021, a prescription for a covered Medicare Part D drug under a prescription drug plan or a Medicare Advantage plan for a Schedule II through V CDS must be

transmitted electronically in accordance with an electronic prescription drug program that meets certain requirements, with specified exceptions.

State Expenditures: The Secretary of Health, in collaboration with MHCC, must 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, MDH general fund expenditures increase by \$10,000 in fiscal 2022 to establish a database to accept and process waiver applications. General fund expenditures also increase, likely minimally, to issue waivers to health care practitioners.

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) or obtain a waiver from the Secretary (valid only for a year).

Additional Information

Prior Introductions: HB 409 of 2019, a similar bill, received a hearing in the House Health and Government Operations Committee, but no further action was taken on the bill. Its cross file, SB 469, received a hearing in the Senate Finance Committee, but no further action was taken on the bill. HB 1416 of 2018, a similar bill, was withdrawn.

Designated Cross File: None.

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

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