

Department of Legislative Services
Maryland General Assembly
2024 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 246

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

Finance

**Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing
Order Program - Establishment**

This departmental bill establishes a Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program. The program must authorize (1) a licensed pharmacist to prescribe and dispense nPEP under specified circumstances and (2) a licensed health care provider to dispense nPEP and delegate the dispensing of nPEP to an employee or volunteer of a “private or public entity” under a written agreement. The Maryland Department of Health (MDH) may administer the program, collect fees, establish guidelines for conducting patient education and training, and collect and report data on the program. MDH must adopt regulations necessary for the administration of the program.

Fiscal Summary

State Effect: MDH can implement the program with existing budgeted resources. To the extent MDH collects fees, general fund revenues increase by an indeterminate amount. To the extent the program results in increased utilization of nPEP drugs for Medicaid enrollees, Medicaid expenditures (and associated federal matching revenues) increase in the near term; however, such expenditures are likely offset by indeterminate savings due to the prevention of HIV infections.

Local Effect: Local health departments (LHDs) may participate in the program as a private or public entity. Any impact on LHDs is likely operational only.

Small Business Effect: MDH has determined that this bill has minimal or no impact on small business (attached). The Department of Legislative Services concurs with this assessment.

Analysis

Bill Summary:

Definitions

“Nonoccupational postexposure prophylaxis” means medication used in accordance with U.S. Centers for Disease Control and Prevention (CDC) Guidelines to reduce the chances of a patient developing HIV after potential exposure to the disease. “Private or public entity” means a health care provider, LHD, community-based organization, or other person that addresses medical or social issues related to HIV exposure. “Standing order” means a directive authorizing pharmacists and health care providers to dispense the nPEP regimens listed in the order without a prescription.

Nonoccupational Postexposure Prophylaxis Standing Order Program

The program must (1) authorize a pharmacist registered with the program to dispense nPEP through a standing order; (2) authorize a licensed health care provider with prescribing authority to prescribe and dispense nPEP through a standing order; and (3) operate in accordance with the procedures approved by MDH with the advice and approval of the State Board of Pharmacy (MBOP).

MDH may (1) collect fees necessary for the administration of the program; (2) administer the program and establish a standardized set of guidelines for participating private and public entities to use in developing and conducting patient education and training on nPEP that includes specified topics; and (3) collect and report data on the operation and results of the program.

Pharmacist Dispensing of Nonoccupational Postexposure Prophylaxis

The definition of “practice pharmacy” is expanded to include prescribing and dispensing nPEP approved by the U.S. Food and Drug Administration in accordance with CDC guidelines if the pharmacist is registered with the program.

At the time of dispensing nPEP, a pharmacist registered with the program must (1) screen the patient to determine that HIV exposure occurred within 72 hours before the dispensing; (2) determine whether the patient meets clinical criteria consistent with CDC guidelines, including the identification of any contraindicated medications; (3) determine whether an available standing order is appropriate for the patient and dispense nPEP in accordance with CDC guidelines; (4) refer the patient to a disease intervention specialist within MDH for ongoing treatment; and (5) determine whether the patient has a primary care provider

and, if so, notify the provider that the patient was dispensed nPEP or, if not, provide the patient with a list of primary care providers and clinics.

If an available standing order is not appropriate for the patient, the pharmacist must refer the patient to a primary care provider. A pharmacist may dispense nPEP in accordance with a drug therapy management contract.

Health Care Provider Dispensing of Nonoccupational Postexposure Prophylaxis

Any licensed health care provider who has dispensing authority may dispense nPEP to an individual in accordance with a standing order under the bill.

A licensed health care provider with prescribing authority who is registered with the program may delegate the dispensing of nPEP under a standing order to an employee or a volunteer of an authorized private or public entity in accordance with a written agreement.

Written Agreements

An authorized private or public entity must enter into a written agreement with a licensed health care provider with prescribing authority to establish protocols for the prescribing and dispensing of nPEP to any individual in accordance with the bill.

Current Law:

Practice of Pharmacy

An individual must be licensed by MBOP to practice pharmacy in the State. The practice of pharmacy includes compounding, dispensing, or distributing prescription drugs or devices; monitoring prescriptions; providing information, explanation, and recommendations to patients and health care practitioners about the safe and effective use of prescription drugs or devices; providing drug therapy management; administering vaccinations; prescribing and dispensing certain contraceptive medications and devices; and administering a self-administered drug to a patient in accordance with regulations adopted by the board.

Prohibition on Prior Authorization for Postexposure Prophylaxis

Chapter 684 of 2022 prohibits carriers and Medicaid managed care organizations from applying a prior authorization requirement for a prescription drug used as postexposure prophylaxis (or PEP) for the prevention of HIV if the prescription drug is prescribed for use in accordance with CDC guidelines.

Opioid Response Program

MDH's Overdose Response Program provides a means of authorizing certain individuals to administer an opioid overdose reversal drug. An authorized private or public entity must enter into a written agreement with a licensed health care provider with prescribing authority to establish protocols for the prescribing and dispensing of an opioid overdose reversal drug approved in accordance with the program.

A licensed health care provider with prescribing authority may prescribe and dispense opioid overdose reversal drugs by issuing a standing order if the licensed health care provider is employed by MDH or an LHD or has a written agreement with an authorized private or public entity. A licensed health care provider with prescribing authority who issues a standing order may delegate the dispensing of opioid overdose reversal drugs to an employee or a volunteer of an authorized private or public entity in accordance with a written agreement.

Background: MDH advises that nPEP is a 28-day course of three antiretroviral medications that an individual must begin taking within 72 hours of exposure to HIV in order to prevent transmission. However, nPEP currently requires a prescription, which presents a barrier to accessing the medication within the window of efficacy.

The bill allows a licensed pharmacist registered with the program to prescribe and dispense nPEP and for employees or volunteers of private and public entities to dispense nPEP under a written agreement. The bill is based on MDH's Opioid Response Program and the statewide standing order for opioid overdose reversal drugs.

Additional Information

Recent Prior Introductions: Similar legislation has not been introduced within the past three years.

Designated Cross File: HB 127 (Chair, Health and Government Operations Committee)(By Request - Departmental - Health) - Health and Government Operations.

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

Fiscal Note History: First Reader - January 26, 2024
km/ljm

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ANALYSIS OF ECONOMIC IMPACT ON SMALL BUSINESSES
Maryland Department of Health
Session 2024

BILL TITLE: **Public Health - Nonoccupational Postexposure Prophylaxis (nPEP)
Standing Order Program - Establishment**

**BILL
NUMBER:** SB 246

**PREPARED
BY:**
(Program\Unit): Prevention and Health Promotion Administration

PART A. ECONOMIC IMPACT RATING

This agency estimates that the proposed bill:

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

The proposal has no economic impact.