

Department of Legislative Services
Maryland General Assembly
2021 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 828 (Senator Lam)
Education, Health, and Environmental Affairs
and Finance

**HIV Prevention Drugs – Dispensing by Pharmacists and Insurance
Requirements**

This bill authorizes a licensed pharmacist to dispense up to a 60-day supply of “preexposure prophylaxis” (PrEP) or a complete course of “postexposure prophylaxis” (PEP) to a patient without a prescription under specified circumstances if the pharmacist completes a training program approved by the State Board of Pharmacy. Medicaid must provide, subject to the limitations of the State budget, medically appropriate drugs approved by the U.S. Food and Drug Administration (FDA) for HIV prevention, including a 60-day supply of PrEP without a prescription and PEP. Insurers, nonprofit health service plans, and health maintenance organizations (collectively known as carriers), and Medicaid managed care organizations (MCOs) are prohibited from (1) requiring prior authorization for PrEP dispensed for HIV prevention dispensed with a prescription, up to a 60-day supply of PrEP dispensed without a prescription, or PEP for HIV prevention and (2) imposing any cost-sharing requirements for certain services related to PrEP and PEP, as specified. **The bill’s insurance provisions take effect January 1, 2022, and apply to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after that date.**

Fiscal Summary

State Effect: Minimal increase in special fund revenues for the Maryland Insurance Administration in FY 2022 from the \$125 rate and form filing fee; contractual assistance is required in FY 2022 only. To the extent the prohibition on prior authorization and cost-sharing results in substantial increases in utilization, Medicaid expenditures (61% federal funds, 39% general funds) increase by an indeterminate amount (and federal fund revenues increase accordingly) beginning in FY 2022; however, Medicaid may realize

savings due to the prevention of HIV infections. Any impact on the State Employee and Retiree Health and Welfare Benefits Program is indeterminate, as discussed below.

Local Effect: Any impact on local government finances is indeterminate and not likely to be meaningful.

Small Business Effect: Meaningful.

Analysis

Bill Summary:

Preexposure Prophylaxis

PrEP means any drug combination provided to a HIV-negative person to prevent HIV infection as defined by the state boards of nursing, pharmacy, or physicians, or the U.S. Centers for Disease Control and Prevention (CDC) guidelines for PrEP.

A pharmacist may dispense up to a 60-day supply of PrEP without a prescription if the patient is (1) HIV negative (as documented in a specified manner) and (2) completes a self-screening assessment tool and reports no specified signs or symptoms of acute HIV infection and is not taking any contraindicated medications.

A pharmacist must provide the patient with (1) counseling on the ongoing use of PrEP, as specified, and (2) oral and written notice that the patient must be seen by a health care provider to receive a prescription for PrEP and that a pharmacist may not dispense a combined 60-day supply of PrEP to a single patient more than once every two years.

A pharmacist must (1) record the dispensing of PrEP in any electronic health record maintained on the patient by the pharmacist; (2) provide the patient with a copy of the record of the encounter that includes specified information; and (3) provide notice to the patient's primary care provider of the encounter with the patient (or provide the patient with a list of health care providers to contact regarding ongoing care for PrEP). A pharmacist may not allow the patient to refuse or waive any required consultation.

Postexposure Prophylaxis

PEP means any drug combination used to prevent HIV infection following an exposure or potential exposure to HIV as defined by the state boards of nursing, pharmacy, or physicians, or CDC guidelines for PEP.

A pharmacist may dispense a complete course of PEP to a patient without a prescription if the pharmacist (1) screens the patient and determines that exposure to HIV occurred within the immediately preceding 72 hours and the patient otherwise meets CDC clinical criteria for PEP; (2) provides HIV testing or obtains patient consent to submit to an HIV test, as specified; (3) provides specified counseling to the patient on the use of PEP and the availability of PrEP; and (4) provides notice to the patient's primary care provider of the PEP treatment (or provides the patient with a list of health care providers to contact regarding follow-up care for PEP). A pharmacist may not allow the patient to refuse or waive any required consultation.

If the patient refuses to consent to an HIV test, but otherwise meets the criteria for PEP, a pharmacist may dispense PEP to the patient.

Training for Pharmacists

A pharmacist must complete a board-approved training program on the use of PrEP and PEP before dispensing either to a patient. The training program must include information about financial assistance programs for PrEP and PEP. The board must consult with the State Board of Physicians and other relevant stakeholders when developing or approving training programs.

Prohibition on Cost-sharing by Carriers

Carriers and Medicaid MCOs may not impose any cost-sharing requirements for medically necessary and appropriate services related to the use of PEP or PrEP, including HIV testing, kidney function testing, ongoing follow-up and monitoring every three months, pregnancy testing, provider office and telehealth visits for prescribing and medication management, serologic laboratory testing for hepatitis B and hepatitis C, testing for other sexually transmitted infections, and vaccinations for hepatitis B.

Current Law: An individual must be licensed by the State Board of Pharmacy 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.

Chapters 820 and 821 of 2017 expanded the scope of practice for a licensed pharmacist, who meets specified requirements, to include prescribing and dispensing contraceptive medications and self-administered contraceptive devices approved by the FDA.

The Drug Therapy Management Program authorizes physicians and pharmacists to enter into a therapy management contract that specifies treatment protocols for patient care. An authorized prescriber who has entered into such an agreement must submit specified documentation to the State Board of Pharmacy.

State Fiscal Effect:

Medicaid

Medicaid currently covers three PrEP drugs. Costs for these drugs in the fee-for-service (FFS) program range from \$1,378 to \$1,876 for a 30-day supply. Medicaid also covers the cost of four PEP drug regimens. Costs in FFS range from \$2,858 to \$4,762 for a 28-day course of treatment.

FFS Medicaid does not require prior authorization for HIV prevention drugs. All nine MCOs cover PrEP and PEP prescription drugs; however, some MCOs have implemented prior authorization requirements or designated certain generic drugs as preferred drugs and certain brand-name drugs as nonpreferred drugs.

Medicaid requires a \$1 copayment for preferred or generic drugs and a \$3 copayment for brand-name or nonpreferred drugs. Copayments are waived for pregnant women and children. Currently, six of the nine MCOs waive copayments for Medicaid participants. If a participant cannot afford to pay a pharmaceutical copayment, a pharmacist must dispense the drug without collecting a copayment.

Medicaid advises that, to the extent the bill's prohibition on prior authorization and cost-sharing relating to PrEP and PEP results in substantial increases in the utilization of these HIV prevention drugs, MCO costs increase, requiring an increase in Medicaid expenditures (61% federal funds, 39% general funds) and a corresponding increase in federal fund revenues, to increase MCO capitation rates in the near term. However, over time, the Maryland Department of Health may realize savings due to the prevention of HIV infections due to the use of PrEP and PEP drugs. Any specific impact is indeterminate and cannot be reliably estimated at this time.

State Employee and Retiree Health and Welfare Benefits Program

The State Employee and Retiree Health and Welfare Benefits Program covers PrEP and PEP drugs without prior authorization. However, the Department of Budget and Management (DBM) advises the bill has the potential to disrupt and/or delay a patient's need for ongoing care and disease management by allowing a patient to receive treatment outside of the individual's health care provider and obtain treatment via multiple

pharmacies within the same two-year period. DBM notes that this may result in increased medical expenditures. However, any such impact is indeterminate.

Small Business Effect: Small business pharmacies may dispense PrEP and PEP drugs without a prescription, as specified.

Additional Information

Prior Introductions: None.

Designated Cross File: None.

Information Source(s): Department of Budget and Management; Maryland Department of Health; Maryland Insurance Administration; Department of Legislative Services

Fiscal Note History: First Reader - March 1, 2021
rh/ljm

Analysis by: Jennifer B. Chasse

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