

Department of Legislative Services
Maryland General Assembly
2022 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

Senate Bill 355

(Senators Lam and Hayes)

Education, Health, and Environmental Affairs
and Finance

Health and Government Operations

**HIV Prevention Drugs - Prescribing and Dispensing by Pharmacists and
Insurance Requirements**

This bill authorizes a licensed pharmacist to prescribe and dispense up to a 30-day supply of “preexposure prophylaxis” (PrEP) or a complete course of “postexposure prophylaxis” (PEP) to a patient under specified circumstances if the pharmacist completes a training program approved by the State Board of Pharmacy (MBOP). Medicaid must provide medically appropriate drugs approved by the U.S. Food and Drug Administration (FDA) for HIV prevention, including PrEP and PEP. Insurers, nonprofit health service plans, and health maintenance organizations (collectively known as carriers) as well as Medicaid managed care organizations (MCOs) are prohibited from (1) requiring prior authorization or step therapy for PrEP or PEP for HIV prevention and (2) imposing any cost-sharing requirements for PrEP or PEP, including certain services related to PrEP and PEP, as specified. **The bill’s insurance provisions take effect January 1, 2023, and apply to all policies, contracts, and health benefit plans that are not grandfathered 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 2023 from the \$125 rate and form filing fee. Minimal increase in MBOP special fund expenditures in FY 2023 only to develop training and adopt regulations. To the extent the prohibition on prior authorization and cost-sharing substantially increases utilization, Medicaid expenditures (61% federal funds, 39% general funds) increase by an indeterminate amount (and federal fund revenues increase accordingly) beginning in FY 2023; 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 approved by FDA that is (1) provided to an HIV-negative person to prevent HIV infection and (2) administered in accordance with the U.S. Centers for Disease Control and Prevention (CDC) guidelines for PrEP.

A pharmacist may prescribe and dispense up to a 30-day supply of PrEP if the patient (1) is 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, if the pharmacist has dispensed a combined 60-day supply to the patient, the patient must be seen by a health care provider to receive any subsequent prescriptions for PrEP.

A pharmacist must (1) record the prescribing and 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 (or provide the patient with a list of health care providers to contact regarding ongoing care for PrEP, including providers that receive funding from the federal Ryan White HIV/AIDS Program). A pharmacist may not allow the patient to refuse or waive any required consultation.

A pharmacist may not prescribe more than a combined 60-day supply of PrEP to the same patient within a two-year period or dispense more than a combined 60-day supply to a patient without a prescription from a health care provider.

Postexposure Prophylaxis

PEP means any drug combination approved by FDA that is (1) used to prevent HIV infection following an exposure or potential exposure to HIV and (2) administered in accordance with CDC guidelines for PEP.

A pharmacist may prescribe and dispense a complete course of PEP to a patient 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, including providers and clinics that receive funding from the federal Ryan White HIV/AIDS Program). 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 prescribe and 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 prescribing and dispensing either to a patient. The training program must include information about financial assistance programs for PrEP and PEP. MBOP must consult with the State Board of Physicians (MBP), the State Board of Nursing (MBON), and other relevant stakeholders when developing or approving training programs. MBOP, in consultation with MBP and MBON, must adopt regulations establishing procedures for creating and disseminating a list of entities that receive funding, either directly or indirectly, from the federal Ryan White HIV/AIDS Program that pharmacists must provide to patients.

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 PrEP or PEP, 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 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.

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 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 MBOP.

State Fiscal Effect:

State Board of Pharmacy

Under the bill, MBOP must consult with MBP, MBON, and other relevant stakeholders when developing or approving training programs and adopt regulations (in consultation with MBP and MBON) establishing procedures for creating and disseminating a list of entities that receive funding, either directly or indirectly, from the federal Ryan White HIV/AIDS Program that pharmacists must provide to patients. MBOP advises, that to develop a training program for pharmacists on the use, prescribing, and dispensing of PrEP and PEP and to adopt related regulations, the board requires additional resources, likely a consultant or part-time contractual position. Thus, MBOP special fund expenditures increase by a minimal amount in fiscal 2023 only.

Medicaid

Medicaid currently covers three PrEP drugs. Costs for these drugs in the fee-for-service (FFS) program range from \$72.90 to \$3,700 for a 30-day supply. Medicaid also covers the cost of four PEP drug regimens. Costs in FFS range from \$80.10 to \$3,759 for a 28-day course of treatment.

FFS Medicaid does not require prior authorization for HIV prevention drugs. All MCOs cover PrEP and PEP prescription drugs; however, some MCOs have implemented prior authorization requirements.

All HIV drugs under both MCOs and FFS have a \$1 copayment. Copayments are waived for pregnant women and children. 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: SB 828 of 2021, a similar bill, received a hearing in the Senate Education, Health, and Environmental Affairs Committee, but no further action was taken.

Designated Cross File: None.

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

Fiscal Note History:
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Analysis by: Jennifer B. Chasse

Direct Inquiries to:

(410) 946-5510

(301) 970-5510