

Department of Legislative Services
Maryland General Assembly
2023 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 64
Finance

(Senator Lam)

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

This bill authorizes a licensed pharmacist to prescribe and dispense “postexposure prophylaxis” (PEP) medications 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 “preexposure prophylaxis” (PrEP) 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 or step therapy for PrEP and (2) imposing any cost-sharing requirements for PrEP or PEP, including certain services, as specified. **The bill’s insurance provisions take effect January 1, 2024, 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 2024 from the \$125 rate and form filing fee. Minimal increase in MBOP special fund expenditures in FY 2024 only to develop training and adopt regulations. To the extent utilization of HIV prevention drugs increases, 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. Any impact on the State Employee and Retiree Health and Welfare Benefits Program is indeterminate, as discussed below.

Local Effect: Any impact on health care expenditures for local governments that purchase fully insured health benefit plans is indeterminate and not likely to be meaningful. Revenues are not affected.

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.

Postexposure Prophylaxis

PEP 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 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

Before prescribing and dispensing PEP to a patient, a pharmacist must complete a board-approved training program on the availability of PrEP and the use of PEP. 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:

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 MCOs from applying a prior authorization requirement for a prescription drug used as PEP for the prevention of HIV if the prescription drug is prescribed for use in accordance with CDC guidelines.

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 availability of PrEP and the use of PEP and to adopt related regulations, the board requires additional resources, likely a part-time contractual health policy analyst. Thus, MBOP special fund expenditures increase by a minimal amount in fiscal 2024 only.

Medicaid

Medicaid currently covers the cost of the PrEP drugs Truvada (emtricitabine/tenofovir disoproxil fumarate), Descovy (emtricitabine/tenofovir alafenamide), generic forms of these drugs, and Apretude (cabotegravir). Costs for these drugs in the fee-for-service (FFS) program range from \$25 to \$37,555 for a 30-day supply. Medicaid also covers the cost of PEP drug regimens. The following drugs are combined with brand-name or generic Truvada: Isentress (raltegravir); Tivicay (dolutegravir); Prezista (darunavir); ritonavir; and Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate). Costs in FFS range from \$80 to \$3,640 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. Per Chapter 684 of 2022, MCOs may not impose prior authorization requirements for PEP; however, some MCOs have prior authorization requirements for PrEP.

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 for PrEP and cost-sharing relating to PrEP and PEP results in substantial increases in the utilization of 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 from 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 drugs without prior authorization at a cost of \$1,100 for a 30-day supply. 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 oversight and coordination of the individual's health care provider and obtain treatment via multiple pharmacies. DBM notes that this may result in increased medical expenditures. However, any such impact is indeterminate.

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

Additional Information

Prior Introductions: Similar legislation has been introduced within the last three years. See SB 355 of 2022 and SB 828 of 2021.

Designated Cross File: None.

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

Fiscal Note History: First Reader - January 26, 2023
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