A BILL ENTITLED

AN ACT concerning

HIV Prevention Drugs – Dispensing by Pharmacists and Insurance Requirements

FOR the purpose of authorizing pharmacists to dispense a certain supply of certain drugs for HIV prevention to a patient without a prescription under certain circumstances; prohibiting a pharmacist from allowing a patient to refuse or waive a certain consultation; requiring a pharmacist, before dispensing a certain drug for HIV prevention, to require the patient to submit evidence of the result of a certain test or submit to a certain test; requiring a pharmacist to take certain actions under certain circumstances if the pharmacist orders a certain test for a patient; requiring a certain pharmacist to complete a certain training program approved by the State Board of Pharmacy before dispensing certain drugs for HIV prevention; requiring that a certain training program include certain information; requiring the Board to consult certain stakeholders when developing or approving a certain training program; requiring the Maryland Medical Assistance Program to provide certain drugs for HIV prevention subject to certain conditions; prohibiting certain insurers, nonprofit health service plans, and health maintenance organizations from requiring prior authorization for certain drugs for HIV prevention or applying cost–sharing requirements for certain services related to the use of certain drugs for HIV prevention; applying certain provisions of this Act to managed care organizations; defining certain terms; providing for the application of certain provisions of this Act; providing for a delayed effective date for certain provisions of this Act; and generally relating to HIV prevention drugs.

BY adding to Article – Health Occupations Section 12–513 Annotated Code of Maryland (2014 Replacement Volume and 2020 Supplement)
BY repealing and reenacting, without amendments,
Article – Health – General
Section 15–102.3(j) and 15–103(a)(2)(xvii)
Annotated Code of Maryland
(2019 Replacement Volume and 2020 Supplement)

BY repealing and reenacting, with amendments,
Article – Health – General
Section 15–103(a)(1)
Annotated Code of Maryland
(2019 Replacement Volume and 2020 Supplement)

BY repealing and reenacting, with amendments,
Article – Health – General
Section 15–103(a)(2)(xv) and (xvi)
Annotated Code of Maryland
(2019 Replacement Volume and 2020 Supplement)

BY adding to
Article – Insurance
Section 15–856
Annotated Code of Maryland
(2017 Replacement Volume and 2020 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
That the Laws of Maryland read as follows:

Article – Health Occupations

12–513.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS
INDICATED.

(2) “CDC GUIDELINES FOR POSTEXPOSURE PROPHYLAXIS” MEANS
“UPDATED GUIDELINES FOR ANTIRETROVIRAL POSTEXPOSURE PROPHYLAXIS
AFTER SEXUAL, INJECTION DRUG USE, OR OTHER NONOCCUPATIONAL EXPOSURE
TO HIV–UNITED STATES, 2016” OR ANY SUBSEQUENT GUIDELINES, PUBLISHED BY
THE FEDERAL CENTERS FOR DISEASE CONTROL AND PREVENTION.

(3) “CDC GUIDELINES FOR PREEXPOSURE PROPHYLAXIS” MEANS
“PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE
UNITED STATES–2017 UPDATE: A CLINICAL PRACTICE GUIDELINE” OR ANY
SUBSEQUENT GUIDELINES, PUBLISHED BY THE FEDERAL CENTERS FOR DISEASE
CONTROL AND PREVENTION.
(4) “Postexposure prophylaxis” means any drug combination used to prevent HIV infection following an exposure or potential exposure to HIV as defined by:

(I) the Board of Nursing;

(II) the Board of Pharmacy;

(III) the Board of Physicians; or

(IV) the CDC, in the CDC guidelines for postexposure prophylaxis.

(5) “Preexposure prophylaxis” means any drug combination provided to an HIV–negative person to prevent HIV infection as defined by:

(I) the Board of Nursing;

(II) the Board of Pharmacy;

(III) the Board of Physicians; or

(IV) the CDC, in the CDC guidelines for preexposure prophylaxis.

(B) (1) A pharmacist may dispense a 30–day supply, but not more than a 60–day supply, of preexposure prophylaxis to a patient without a prescription if:

(I) the patient is HIV negative as documented by a test in accordance with paragraph (3) of this subsection;

(II) the patient completes a self–screening assessment tool and reports:

1. no signs or symptoms of acute HIV infection from a checklist of acute HIV infection signs and symptoms; and

2. not taking any contraindicated medications;

(III) at the time the preexposure prophylaxis is dispensed, the pharmacist provides:
1. **Counseling to the Patient on the Ongoing Use** of Preexposure Prophylaxis, including education regarding side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for:

A. HIV;

B. Renal Function;

C. Hepatitis B;

D. Hepatitis C;

E. Sexually Transmitted Diseases;

F. Pregnancy for individuals of childbearing capacity; and

2. **Oral and Written Notice to the Patient** that:

A. The patient must be seen by a health care provider to receive a prescription for preexposure prophylaxis; and

B. A pharmacist may not dispense a combined 60-day supply of preexposure prophylaxis to a single patient more than once every 2 years;

(iv) The pharmacist records the dispensing of the preexposure prophylaxis in any electronic health record maintained on the patient by the pharmacist;

(v) The pharmacist provides the patient with a copy of the record of the encounter that includes the patient’s completed self-screening assessment tool and the preexposure prophylaxis dispensed or the basis for not dispensing a preexposure prophylaxis; and

(vi) The pharmacist provides:

1. Notice to the patient’s primary care provider of the encounter with the patient; or
2. IF THE PATIENT DOES NOT HAVE A PRIMARY CARE PROVIDER OR REFUSES TO PROVIDE THE NAME OF A PRIMARY CARE PROVIDER, THE PATIENT WITH A LIST OF PHYSICIANS, CLINICS, OR OTHER HEALTH CARE PROVIDERS TO CONTACT REGARDING ONGOING CARE FOR PREEXPOSURE PROPHYLAXIS.

(2) THE PHARMACIST MAY NOT ALLOW THE PATIENT TO REFUSE OR WAIVE ANY CONSULTATION REQUIRED UNDER PARAGRAPH (1) OF THIS SUBSECTION.

(3) (I) BEFORE DISPENSING A PREEXPOSURE PROPHYLAXIS TO A PATIENT UNDER PARAGRAPH (1) OF THIS SUBSECTION, THE PHARMACIST SHALL REQUIRE THE PATIENT TO:

1. SUBMIT EVIDENCE OF THE PATIENT’S NEGATIVE HIV TEST RESULT OBTAINED WITHIN THE IMMEDIATELY PRECEDING 7 DAYS FROM AN HIV ANTIGEN/ANTIBODY TEST OR ANTIBODY–ONLY TEST OR FROM A RAPID, POINT–OF–CARE FINGERSTICK BLOOD TEST THAT IS APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION; OR

2. SUBMIT TO AN HIV TEST ORDERED BY THE PHARMACIST.

(II) IF A PHARMACIST ORDERS AN HIV TEST FOR A PATIENT UNDER SUBPARAGRAPH (I)2 OF THIS PARAGRAPH AND:

1. THE TEST RESULTS ARE NOT TRANSMITTED DIRECTLY TO THE PHARMACIST, THE PHARMACIST SHALL VERIFY THE TEST RESULTS TO THE PHARMACIST’S SATISFACTION; OR

2. THE PATIENT TESTS POSITIVE FOR HIV INFECTION, THE PHARMACIST SHALL REFER THE PATIENT TO A HEALTH CARE PROVIDER AND PROVIDE A LIST OF HEALTH CARE PROVIDERS AND CLINICS IN THE AREA IN WHICH THE PHARMACY IS LOCATED.

(C) (1) A PHARMACIST MAY DISPENSE A COMPLETE COURSE OF POSTEXPOSURE PROPHYLAXIS TO A PATIENT WITHOUT A PRESCRIPTION IF THE PHARMACIST:

(i) SCREENS THE PATIENT AND DETERMINES:
1. The exposure to HIV occurred within the immediately preceding 72 hours; and

2. The patient otherwise meets the clinical criteria for postexposure prophylaxis consistent with the CDC guidelines for postexposure prophylaxis;

   (II) 1. Provides HIV testing that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988; or

2. Except as provided in paragraph (3) of this subsection, obtains the consent of the patient to submit to an HIV test consistent with the CDC guidelines for postexposure prophylaxis;

   (III) Provides counseling to the patient on:

   1. The use of postexposure prophylaxis consistent with the CDC guidelines for postexposure prophylaxis, including education regarding side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV and sexually transmitted diseases; and

   2. The availability of preexposure prophylaxis for individuals who are at substantial risk of contracting HIV; and

   (IV) Provides:

   1. Notice to the patient’s primary care provider of the postexposure prophylaxis treatment; or

   2. If the patient does not have a primary care provider or refuses to provide the name of a health care provider, the patient with a list of physicians, clinics, or other health care providers to contact regarding follow-up care for postexposure prophylaxis.

   (2) A pharmacist may not allow a patient to refuse or waive a consultation required under paragraph (1) of this subsection.

   (3) If the patient refuses to consent to an HIV test under paragraph (1)(II)2 of this subsection but otherwise meets the criteria
FOR POSTEXPOSURE PROPHYLAXIS UNDER THIS SUBSECTION, THE PHARMACIST MAY DISPENSE POSTEXPOSURE PROPHYLAXIS TO THE PATIENT.

(D) (1) (I) A PHARMACIST SHALL COMPLETE A TRAINING PROGRAM ON THE USE OF PREEXPOSURE PROPHYLAXIS AND POSTEXPOSURE PROPHYLAXIS THAT IS APPROVED BY THE BOARD BEFORE DISPENSING PREEXPOSURE PROPHYLAXIS OR POSTEXPOSURE PROPHYLAXIS TO A PATIENT.

(II) THE TRAINING PROGRAM REQUIRED UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH SHALL INCLUDE INFORMATION ABOUT FINANCIAL ASSISTANCE PROGRAMS FOR PREEXPOSURE PROPHYLAXIS AND POSTEXPOSURE PROPHYLAXIS.

(2) THE BOARD SHALL CONSULT WITH THE STATE BOARD OF PHYSICIANS AND OTHER RELEVANT STAKEHOLDERS, INCLUDING THE MARYLAND CENTER FOR HIV CARE SERVICES, WHEN DEVELOPING OR APPROVING TRAINING PROGRAMS THAT MEET THE REQUIREMENTS OF THIS SUBSECTION.

Article – Health – General

15–103.

(a) (1) The Secretary shall administer the Maryland Medical Assistance Program.

(2) The Program:

(xv) Shall provide, subject to the limitations of the State budget, mental health services appropriately delivered through telehealth to a patient in the patient’s home setting; [and]

(xvi) Beginning on January 1, 2021, shall provide, subject to the limitations of the State budget and § 15–855(b)(2) of the Insurance Article, and as permitted by federal law, services for pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections and pediatric acute onset neuropsychiatric syndrome, including the use of intravenous immunoglobulin therapy, for eligible Program recipients, if pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections and pediatric acute onset neuropsychiatric syndrome are coded for billing and diagnosis purposes in accordance with § 15–855(d) of the Insurance Article; AND

(XVII) SHALL PROVIDE, SUBJECT TO THE LIMITATIONS OF THE STATE BUDGET, MEDICALLY APPROPRIATE DRUGS THAT ARE APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION FOR HIV PREVENTION, INCLUDING:
1. **Preexposure Prophylaxis**, limited to a 60-day supply without a prescription; and

2. **Postexposure Prophylaxis**, as defined in § 12–513 of the **Health Occupations Article**.

Section 2. And be it further enacted, that the Laws of Maryland read as follows:

**Article – Health – General**

15–102.3.

**(J)** The provisions of § 15–856 of the **Insurance Article** apply to managed care organizations in the same manner as they apply to carriers.

**Article – Insurance**

15–856.

**(A)** This section applies to:

1. Insurers and nonprofit health service plans that provide coverage for prescription drugs under individual, group, or blanket health insurance policies or contracts that are issued or delivered in the State; and

2. Health maintenance organizations that provide coverage for prescription drugs under individual or group contracts that are issued or delivered in the State.

**(B)** An entity subject to this section may not require prior authorization for:

1. Preexposure prophylaxis for HIV prevention dispensed with a prescription;

2. Up to a 60-day supply of a preexposure prophylaxis for HIV prevention dispensed without a prescription; or

(C) An entity subject to this section may not impose any cost–sharing requirements, including copayments, coinsurance, or deductibles, for medically necessary and appropriate services related to the use of postexposure prophylaxis or preexposure prophylaxis, including:

1. HIV testing;
2. Kidney function testing;
3. Ongoing follow-up and monitoring every 3 months;
4. Pregnancy testing;
5. Provider office and telehealth visits for prescribing and medication management;
6. Serologic laboratory testing for hepatitis B and hepatitis C viruses;
7. Testing for other sexually transmitted infections, including 3-site testing for gonorrhea and chlamydia; and
8. Vaccinations for hepatitis B.

SECTION 3. AND BE IT FURTHER ENACTED, That Section 2 of this Act shall apply to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after January 1, 2022.

SECTION 4. AND BE IT FURTHER ENACTED, That Section 2 of this Act shall take effect January 1, 2022.

SECTION 5. AND BE IT FURTHER ENACTED, That, except as provided in Section 4 of this Act, this Act shall take effect October 1, 2021.