SENATE BILL 355

SB 828/21 – EHE & FIN

By: Senator Lam
Introduced and read first time: January 21, 2022
Assigned to: Education, Health, and Environmental Affairs and Finance

A BILL ENTITLED

AN ACT concerning
HIV Prevention Drugs – Prescribing and Dispensing by Pharmacists and Insurance Requirements

FOR the purpose of authorizing pharmacists to prescribe and dispense preexposure prophylaxis and postexposure prophylaxis for HIV prevention to patients under certain circumstances; requiring the Maryland Medical Assistance Program to provide drugs that are approved by the United States Food and Drug Administration for HIV prevention; prohibiting managed care organizations, insurers, nonprofit health service plans, and health maintenance organizations from requiring prior authorization, step therapy, or cost–sharing for preexposure prophylaxis for HIV prevention or postexposure prophylaxis for HIV prevention; and generally relating to HIV prevention drugs.

BY repealing and reenacting, with amendments,
Article – Health Occupations
Section 12–101(x)(1)(xi) and (xii)
Annotated Code of Maryland
(2021 Replacement Volume)

BY adding to
Article – Health Occupations
Section 12–101(x)(1)(xiii) and 12–514
Annotated Code of Maryland
(2021 Replacement Volume)

BY repealing and reenacting, without amendments,
Article – Health – General
Section 15–103(a)(1)
Annotated Code of Maryland
(2019 Replacement Volume and 2021 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW. [Brackets] indicate matter deleted from existing law.
BY repealing and reenacting, with amendments,
Article – Health – General
Section 15–103(a)(2)(xvi) and (xvii)
Annotated Code of Maryland
(2019 Replacement Volume and 2021 Supplement)

BY adding to
Article – Health – General
Section 15–102.3(j) and 15–103(a)(2)(xviii)
Annotated Code of Maryland
(2019 Replacement Volume and 2021 Supplement)

BY adding to
Article – Insurance
Section 15–856
Annotated Code of Maryland
(2017 Replacement Volume and 2021 Supplement)

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

Article – Health Occupations

12–101.

(x) (1) “Practice pharmacy” means to engage in any of the following activities:

(xi) Providing drug therapy management in accordance with §
19–713.6 of the Health – General Article; OR

(xii) Prescribing and dispensing contraceptive medications and
self–administered contraceptive devices approved by the U.S. Food and Drug
Administration; OR

(XIII) PRESCRIBING AND DISPENSING PREEXPOSURE
PROPHYLAXIS AND POSTEXPOSURE PROPHYLAXIS MEDICATIONS FOR HIV
APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION.

12–514.

(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 APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION THAT IS:

(I) USED TO PREVENT HIV INFECTION FOLLOWING AN
EXPOSURE OR POTENTIAL EXPOSURE TO HIV; AND

(II) ADMINISTERED IN ACCORDANCE WITH THE CDC, IN THE
CDC GUIDELINES FOR POSTEXPOSURE PROPHYLAXIS.

(5) “PREEXPOSURE PROPHYLAXIS” MEANS ANY DRUG COMBINATION
APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION THAT IS:

(I) PROVIDED TO AN HIV—NEGATIVE PERSON TO PREVENT
HIV INFECTION; AND

(II) ADMINISTERED IN ACCORDANCE WITH THE CDC, IN THE
CDC GUIDELINES FOR PREEXPOSURE PROPHYLAXIS.

(6) “RYAN WHITE HIV/AIDS PROGRAM” MEANS THE PROGRAM
ADMINISTERED BY THE FEDERAL HEALTH RESOURCES AND SERVICES
ADMINISTRATION THAT PROVIDES GRANTS TO PROVIDE CARE AND TREATMENT
SERVICES TO INDIVIDUALS WITH HIV TO IMPROVE HEALTH OUTCOMES AND
REDUCE HIV TRANSMISSION AMONG HARD–TO–REACH POPULATIONS.

(B) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, A
PHARMACIST MAY PRESCRIBE AND DISPENSE UP TO A 30–DAY SUPPLY OF
PREEXPOSURE PROPHYLAXIS TO A PATIENT 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; and
   F. Pregnancy for individuals of childbearing capacity; and

2. Oral and written notice to the patient 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 preexposure prophylaxis;

(IV) The pharmacist records the prescribing and 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 prescribed and 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 IN THE AREA THAT RECEIVE FUNDING, EITHER DIRECTLY OR INDIRECTLY, FROM THE Ryan White HIV/AIDS Program TO CONTACT REGARDING ONGOING CARE FOR PREEXPOSURE PROPHYLAXIS.**

   (2) **THE PHARMACIST MAY NOT:**

   (I) ALLOW THE PATIENT TO REFUSE OR WAIVE ANY CONSULTATION REQUIRED UNDER PARAGRAPH (1) OF THIS SUBSECTION;

   (II) PRESCRIBE MORE THAN A COMBINED 60–DAY SUPPLY OF PREEXPOSURE PROPHYLAXIS TO THE SAME PATIENT WITHIN A 2–YEAR PERIOD; OR

   (III) DISPENSE MORE THAN A COMBINED 60–DAY SUPPLY TO A PATIENT WITHOUT A PRESCRIPTION FROM A HEALTH CARE PROVIDER.

(3) (I) **BEFORE PRESCRIBING AND 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 U.S. Food AND Drug Administration; OR**

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

   (II) 1. **IF A PHARMACIST ORDERS AN HIV TEST FOR A PATIENT UNDER SUBPARAGRAPH (I)2 OF THIS PARAGRAPH AND THE TEST RESULTS ARE NOT TRANSMITTED DIRECTLY TO THE PHARMACIST, THE PHARMACIST SHALL VERIFY THE TEST RESULTS TO THE PHARMACIST’S SATISFACTION.**

   2. **IF A PHARMACIST ORDERS AN HIV TEST FOR A PATIENT UNDER SUBPARAGRAPH (I)2 OF THIS PARAGRAPH AND 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 THAT RECEIVE
FUNDING, EITHER DIRECTLY OR INDIRECTLY, FROM THE RYAN WHITE HIV/AIDS
PROGRAM.

(C) (1) A PHARMACIST MAY PRESCRIBE AND DISPENSE A COMPLETE
COURSE OF POSTEXPOSURE PROPHYLAXIS TO A PATIENT 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
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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 IN THE AREA THAT RECEIVE FUNDING, EITHER DIRECTLY OR INDIRECTLY, FROM THE RYAN WHITE HIV/AIDS PROGRAM 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 PRESCRIBE AND 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 PRESCRIBING AND 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, THE STATE BOARD OF NURSING, 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.

(E) THE BOARD, IN CONSULTATION WITH THE STATE BOARD OF PHYSICIANS AND THE STATE BOARD OF NURSING, SHALL ADOPT REGULATIONS ESTABLISHING PROCEDURES FOR CREATING AND DISSEMINATING A LIST OF ENTITIES THAT RECEIVE FUNDING, EITHER DIRECTLY OR INDIRECTLY, FROM THE RYAN WHITE HIV/AIDS PROGRAM.

Article – Health – General

15–103.

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

(2) The Program:
(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) Beginning on January 1, 2022, may not include, subject to federal approval and limitations of the State budget, a frequency limitation on covered dental prophylaxis care or oral health exams that requires the dental prophylaxis care or oral health exams to be provided at an interval greater than 120 days within a plan year; AND

(XVIII) SHALL PROVIDE, SUBJECT TO THE LIMITATIONS OF THE STATE BUDGET, MEDICALLY APPROPRIATE DRUGS THAT ARE APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION FOR HIV PREVENTION, INCLUDING:

1. Preexposure prophylaxis; 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) (1) In this section the following words have the meanings indicated.

(2) “Postexposure prophylaxis” means any drug combination approved by the U.S. Food and Drug Administration that is:
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(1) used to prevent HIV infection following an exposure or a potential exposure to HIV; and

(II) administered in accordance with CDC guidelines for postexposure prophylaxis, as defined in § 12–514 of the Health Occupations Article.

(3) "Preexposure prophylaxis" means any drug combination approved by the U.S. Food and Drug Administration that is:

(I) provided to an HIV–negative person to prevent HIV infection; and

(II) administered in accordance with the CDC guidelines for preexposure prophylaxis, as defined in § 12–514 of the Health Occupations Article.

(B) (1) Except as provided in paragraph (2) of this subsection, this section applies to:

(I) 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

(II) health maintenance organizations that provide coverage for prescription drugs under individual or group contracts that are issued or delivered in the State.

(2) This section does not apply to a grandfathered plan, as defined in § 1251 of the Affordable Care Act.

(C) An entity subject to this section may not require prior authorization or step therapy or impose any cost–sharing requirements, including copayments, coinsurance, or deductibles, for:

(1) preexposure prophylaxis for HIV prevention; or

(2) postexposure prophylaxis for HIV prevention.

(D) 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 THREE–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 that are not grandfathered plans as defined in § 1251 of the Affordable Care Act issued, delivered, or renewed in the State on or after January 1, 2023.

SECTION 4. AND BE IT FURTHER ENACTED, That Section 2 of this Act shall take effect January 1, 2023.

SECTION 5. AND BE IT FURTHER ENACTED, That, except as provided in Section 4 of this Act, this Act shall take effect October 1, 2022.