

SENATE BILL 355

J2, J5, J4
SB 828/21 – EHE & FIN

2lr1109

By: **Senator Lam**

Introduced and read first time: January 21, 2022

Assigned to: Education, Health, and Environmental Affairs and Finance

A BILL ENTITLED

1 AN ACT concerning

2 **HIV Prevention Drugs – Prescribing and Dispensing by Pharmacists and**
3 **Insurance Requirements**

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

13 BY repealing and reenacting, with amendments,
14 Article – Health Occupations
15 Section 12–101(x)(1)(xi) and (xii)
16 Annotated Code of Maryland
17 (2021 Replacement Volume)

18 BY adding to
19 Article – Health Occupations
20 Section 12–101(x)(1)(xiii) and 12–514
21 Annotated Code of Maryland
22 (2021 Replacement Volume)

23 BY repealing and reenacting, without amendments,
24 Article – Health – General
25 Section 15–103(a)(1)
26 Annotated Code of Maryland
27 (2019 Replacement Volume and 2021 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 BY repealing and reenacting, with amendments,
 2 Article – Health – General
 3 Section 15–103(a)(2)(xvi) and (xvii)
 4 Annotated Code of Maryland
 5 (2019 Replacement Volume and 2021 Supplement)

6 BY adding to
 7 Article – Health – General
 8 Section 15–102.3(j) and 15–103(a)(2)(xviii)
 9 Annotated Code of Maryland
 10 (2019 Replacement Volume and 2021 Supplement)

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

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

18 **Article – Health Occupations**

19 12–101.

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

21 (xi) Providing drug therapy management in accordance with §
 22 19–713.6 of the Health – General Article; [or]

23 (xii) Prescribing and dispensing contraceptive medications and
 24 self-administered contraceptive devices approved by the U.S. Food and Drug
 25 Administration; **OR**

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

29 12–514.

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

32 **(2) “CDC GUIDELINES FOR POSTEXPOSURE PROPHYLAXIS” MEANS**
 33 **“UPDATED GUIDELINES FOR ANTIRETROVIRAL POSTEXPOSURE PROPHYLAXIS**
 34 **AFTER SEXUAL, INJECTION DRUG USE, OR OTHER NONOCCUPATIONAL EXPOSURE**

1 TO HIV–UNITED STATES, 2016” OR ANY SUBSEQUENT GUIDELINES PUBLISHED BY
2 THE FEDERAL CENTERS FOR DISEASE CONTROL AND PREVENTION.

3 (3) “CDC GUIDELINES FOR PREEXPOSURE PROPHYLAXIS” MEANS
4 “PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE
5 UNITED STATES–2017 UPDATE: A CLINICAL PRACTICE GUIDELINE” OR ANY
6 SUBSEQUENT GUIDELINES PUBLISHED BY THE FEDERAL CENTERS FOR DISEASE
7 CONTROL AND PREVENTION.

8 (4) “POSTEXPOSURE PROPHYLAXIS” MEANS ANY DRUG
9 COMBINATION APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION THAT IS:

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

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

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

16 (I) PROVIDED TO AN HIV–NEGATIVE PERSON TO PREVENT
17 HIV INFECTION; AND

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

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

25 (B) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, A
26 PHARMACIST MAY PRESCRIBE AND DISPENSE UP TO A 30–DAY SUPPLY OF
27 PREEXPOSURE PROPHYLAXIS TO A PATIENT IF:

28 (I) THE PATIENT IS HIV NEGATIVE AS DOCUMENTED BY A TEST
29 IN ACCORDANCE WITH PARAGRAPH (3) OF THIS SUBSECTION;

30 (II) THE PATIENT COMPLETES A SELF–SCREENING
31 ASSESSMENT TOOL AND REPORTS:

1 1. **NO SIGNS OR SYMPTOMS OF ACUTE HIV INFECTION**
2 **FROM A CHECKLIST OF ACUTE HIV INFECTION SIGNS AND SYMPTOMS; AND**

3 2. **NOT TAKING ANY CONTRAINDICATED MEDICATIONS;**

4 **(III) AT THE TIME THE PREEXPOSURE PROPHYLAXIS IS**
5 **DISPENSED, THE PHARMACIST PROVIDES:**

6 1. **COUNSELING TO THE PATIENT ON THE ONGOING USE**
7 **OF PREEXPOSURE PROPHYLAXIS, INCLUDING EDUCATION REGARDING SIDE**
8 **EFFECTS, SAFETY DURING PREGNANCY AND BREASTFEEDING, ADHERENCE TO**
9 **RECOMMENDED DOSING, AND THE IMPORTANCE OF TIMELY TESTING AND**
10 **TREATMENT, AS APPLICABLE, FOR:**

11 A. **HIV;**

12 B. **RENAL FUNCTION;**

13 C. **HEPATITIS B;**

14 D. **HEPATITIS C;**

15 E. **SEXUALLY TRANSMITTED DISEASES; AND**

16 F. **PREGNANCY FOR INDIVIDUALS OF CHILDBEARING**
17 **CAPACITY; AND**

18 2. **ORAL AND WRITTEN NOTICE TO THE PATIENT THAT,**
19 **IF THE PHARMACIST HAS DISPENSED A COMBINED 60-DAY SUPPLY TO THE PATIENT,**
20 **THE PATIENT MUST BE SEEN BY A HEALTH CARE PROVIDER TO RECEIVE ANY**
21 **SUBSEQUENT PRESCRIPTIONS FOR PREEXPOSURE PROPHYLAXIS;**

22 **(IV) THE PHARMACIST RECORDS THE PRESCRIBING AND**
23 **DISPENSING OF THE PREEXPOSURE PROPHYLAXIS IN ANY ELECTRONIC HEALTH**
24 **RECORD MAINTAINED ON THE PATIENT BY THE PHARMACIST;**

25 **(V) THE PHARMACIST PROVIDES THE PATIENT WITH A COPY OF**
26 **THE RECORD OF THE ENCOUNTER THAT INCLUDES THE PATIENT'S COMPLETED**
27 **SELF-SCREENING ASSESSMENT TOOL AND THE PREEXPOSURE PROPHYLAXIS**
28 **PRESCRIBED AND DISPENSED OR THE BASIS FOR NOT DISPENSING A PREEXPOSURE**
29 **PROPHYLAXIS; AND**

30 **(VI) THE PHARMACIST PROVIDES:**

1 1. NOTICE TO THE PATIENT'S PRIMARY CARE PROVIDER
2 OF THE ENCOUNTER WITH THE PATIENT; OR

3 2. IF THE PATIENT DOES NOT HAVE A PRIMARY CARE
4 PROVIDER OR REFUSES TO PROVIDE THE NAME OF A PRIMARY CARE PROVIDER, THE
5 PATIENT WITH A LIST OF PHYSICIANS, CLINICS, OR OTHER HEALTH CARE
6 PROVIDERS IN THE AREA THAT RECEIVE FUNDING, EITHER DIRECTLY OR
7 INDIRECTLY, FROM THE RYAN WHITE HIV/AIDS PROGRAM TO CONTACT
8 REGARDING ONGOING CARE FOR PREEXPOSURE PROPHYLAXIS.

9 (2) THE PHARMACIST MAY NOT:

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

12 (ii) PRESCRIBE MORE THAN A COMBINED 60-DAY SUPPLY OF
13 PREEXPOSURE PROPHYLAXIS TO THE SAME PATIENT WITHIN A 2-YEAR PERIOD; OR

14 (iii) DISPENSE MORE THAN A COMBINED 60-DAY SUPPLY TO A
15 PATIENT WITHOUT A PRESCRIPTION FROM A HEALTH CARE PROVIDER.

16 (3) (i) BEFORE PRESCRIBING AND DISPENSING A PREEXPOSURE
17 PROPHYLAXIS TO A PATIENT UNDER PARAGRAPH (1) OF THIS SUBSECTION, THE
18 PHARMACIST SHALL REQUIRE THE PATIENT TO:

19 1. SUBMIT EVIDENCE OF THE PATIENT'S NEGATIVE HIV
20 TEST RESULT OBTAINED WITHIN THE IMMEDIATELY PRECEDING 7 DAYS FROM AN
21 HIV ANTIGEN/ANTIBODY TEST OR ANTIBODY-ONLY TEST OR FROM A RAPID,
22 POINT-OF-CARE FINGERSTICK BLOOD TEST THAT IS APPROVED BY THE U.S. FOOD
23 AND DRUG ADMINISTRATION; OR

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

26 (ii) 1. IF A PHARMACIST ORDERS AN HIV TEST FOR A
27 PATIENT UNDER SUBPARAGRAPH (I)2 OF THIS PARAGRAPH AND THE TEST RESULTS
28 ARE NOT TRANSMITTED DIRECTLY TO THE PHARMACIST, THE PHARMACIST SHALL
29 VERIFY THE TEST RESULTS TO THE PHARMACIST'S SATISFACTION.

30 2. IF A PHARMACIST ORDERS AN HIV TEST FOR A
31 PATIENT UNDER SUBPARAGRAPH (I)2 OF THIS PARAGRAPH AND THE PATIENT TESTS
32 POSITIVE FOR HIV INFECTION, THE PHARMACIST SHALL REFER THE PATIENT TO A

1 HEALTH CARE PROVIDER AND PROVIDE A LIST OF HEALTH CARE PROVIDERS AND
2 CLINICS IN THE AREA IN WHICH THE PHARMACY IS LOCATED THAT RECEIVE
3 FUNDING, EITHER DIRECTLY OR INDIRECTLY, FROM THE RYAN WHITE HIV/AIDS
4 PROGRAM.

5 (c) (1) A PHARMACIST MAY PRESCRIBE AND DISPENSE A COMPLETE
6 COURSE OF POSTEXPOSURE PROPHYLAXIS TO A PATIENT IF THE PHARMACIST:

7 (i) SCREENS THE PATIENT AND DETERMINES:

8 1. THE EXPOSURE TO HIV OCCURRED WITHIN THE
9 IMMEDIATELY PRECEDING 72 HOURS; AND

10 2. THE PATIENT OTHERWISE MEETS THE CLINICAL
11 CRITERIA FOR POSTEXPOSURE PROPHYLAXIS CONSISTENT WITH THE CDC
12 GUIDELINES FOR POSTEXPOSURE PROPHYLAXIS;

13 (ii) 1. PROVIDES HIV TESTING THAT IS CLASSIFIED AS
14 WAIVED UNDER THE FEDERAL CLINICAL LABORATORY IMPROVEMENT
15 AMENDMENTS OF 1988; OR

16 2. EXCEPT AS PROVIDED IN PARAGRAPH (3) OF THIS
17 SUBSECTION, OBTAINS THE CONSENT OF THE PATIENT TO SUBMIT TO AN HIV TEST
18 CONSISTENT WITH THE CDC GUIDELINES FOR POSTEXPOSURE PROPHYLAXIS;

19 (iii) PROVIDES COUNSELING TO THE PATIENT ON:

20 1. THE USE OF POSTEXPOSURE PROPHYLAXIS
21 CONSISTENT WITH THE CDC GUIDELINES FOR POSTEXPOSURE PROPHYLAXIS,
22 INCLUDING EDUCATION REGARDING SIDE EFFECTS, SAFETY DURING PREGNANCY
23 AND BREASTFEEDING, ADHERENCE TO RECOMMENDED DOSING, AND THE
24 IMPORTANCE OF TIMELY TESTING AND TREATMENT, AS APPLICABLE, FOR HIV AND
25 SEXUALLY TRANSMITTED DISEASES; AND

26 2. THE AVAILABILITY OF PREEXPOSURE PROPHYLAXIS
27 FOR INDIVIDUALS WHO ARE AT SUBSTANTIAL RISK OF CONTRACTING HIV; AND

28 (iv) PROVIDES:

29 1. NOTICE TO THE PATIENT'S PRIMARY CARE PROVIDER
30 OF THE POSTEXPOSURE PROPHYLAXIS TREATMENT; OR

31 2. IF THE PATIENT DOES NOT HAVE A PRIMARY CARE

1 PROVIDER OR REFUSES TO PROVIDE THE NAME OF A HEALTH CARE PROVIDER, THE
2 PATIENT WITH A LIST OF PHYSICIANS, CLINICS, OR OTHER HEALTH CARE
3 PROVIDERS IN THE AREA THAT RECEIVE FUNDING, EITHER DIRECTLY OR
4 INDIRECTLY, FROM THE RYAN WHITE HIV/AIDS PROGRAM TO CONTACT
5 REGARDING FOLLOW-UP CARE FOR POSTEXPOSURE PROPHYLAXIS.

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

8 (3) IF THE PATIENT REFUSES TO CONSENT TO AN HIV TEST UNDER
9 PARAGRAPH (1)(II)2 OF THIS SUBSECTION BUT OTHERWISE MEETS THE CRITERIA
10 FOR POSTEXPOSURE PROPHYLAXIS UNDER THIS SUBSECTION, THE PHARMACIST
11 MAY PRESCRIBE AND DISPENSE POSTEXPOSURE PROPHYLAXIS TO THE PATIENT.

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

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

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

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

30 Article – Health – General

31 15–103.

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

34 (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:

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

3 (II) ADMINISTERED IN ACCORDANCE WITH CDC GUIDELINES
4 FOR POSTEXPOSURE PROPHYLAXIS, AS DEFINED IN § 12-514 OF THE HEALTH
5 OCCUPATIONS ARTICLE.

6 (3) "PREEXPOSURE PROPHYLAXIS" MEANS ANY DRUG COMBINATION
7 APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION THAT IS:

8 (I) PROVIDED TO AN HIV-NEGATIVE PERSON TO PREVENT HIV
9 INFECTION; AND

10 (II) ADMINISTERED IN ACCORDANCE WITH THE CDC
11 GUIDELINES FOR PREEXPOSURE PROPHYLAXIS, AS DEFINED IN § 12-514 OF THE
12 HEALTH OCCUPATIONS ARTICLE.

13 (B) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION,
14 THIS SECTION APPLIES TO:

15 (I) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT
16 PROVIDE COVERAGE FOR PRESCRIPTION DRUGS UNDER INDIVIDUAL, GROUP, OR
17 BLANKET HEALTH INSURANCE POLICIES OR CONTRACTS THAT ARE ISSUED OR
18 DELIVERED IN THE STATE; AND

19 (II) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE
20 COVERAGE FOR PRESCRIPTION DRUGS UNDER INDIVIDUAL OR GROUP CONTRACTS
21 THAT ARE ISSUED OR DELIVERED IN THE STATE.

22 (2) THIS SECTION DOES NOT APPLY TO A GRANDFATHERED PLAN, AS
23 DEFINED IN § 1251 OF THE AFFORDABLE CARE ACT.

24 (C) AN ENTITY SUBJECT TO THIS SECTION MAY NOT REQUIRE PRIOR
25 AUTHORIZATION OR STEP THERAPY OR IMPOSE ANY COST-SHARING
26 REQUIREMENTS, INCLUDING COPAYMENTS, COINSURANCE, OR DEDUCTIBLES, FOR:

27 (1) PREEXPOSURE PROPHYLAXIS FOR HIV PREVENTION; OR

28 (2) POSTEXPOSURE PROPHYLAXIS FOR HIV PREVENTION.

29 (D) AN ENTITY SUBJECT TO THIS SECTION MAY NOT IMPOSE ANY
30 COST-SHARING REQUIREMENTS, INCLUDING COPAYMENTS, COINSURANCE, OR
31 DEDUCTIBLES, FOR MEDICALLY NECESSARY AND APPROPRIATE SERVICES RELATED

1 TO THE USE OF POSTEXPOSURE PROPHYLAXIS OR PREEXPOSURE PROPHYLAXIS,
2 INCLUDING:

3 (1) HIV TESTING;

4 (2) KIDNEY FUNCTION TESTING;

5 (3) ONGOING FOLLOW-UP AND MONITORING EVERY 3 MONTHS;

6 (4) PREGNANCY TESTING;

7 (5) PROVIDER OFFICE AND TELEHEALTH VISITS FOR PRESCRIBING
8 AND MEDICATION MANAGEMENT;

9 (6) SEROLOGIC LABORATORY TESTING FOR HEPATITIS B AND
10 HEPATITIS C VIRUSES;

11 (7) TESTING FOR OTHER SEXUALLY TRANSMITTED INFECTIONS,
12 INCLUDING THREE-SITE TESTING FOR GONORRHEA AND CHLAMYDIA; AND

13 (8) VACCINATIONS FOR HEPATITIS B.

14 SECTION 3. AND BE IT FURTHER ENACTED, That Section 2 of this Act shall
15 apply to all policies, contracts, and health benefit plans that are not grandfathered plans
16 as defined in § 1251 of the Affordable Care Act issued, delivered, or renewed in the State
17 on or after January 1, 2023.

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

20 SECTION 5. AND BE IT FURTHER ENACTED, That, except as provided in Section
21 4 of this Act, this Act shall take effect October 1, 2022.