

SENATE BILL 828

J2, J4, C3

1lr1684

By: **Senator Lam**

Introduced and read first time: February 9, 2021

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

A BILL ENTITLED

1 AN ACT concerning

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

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

24 BY adding to
25 Article – Health Occupations
26 Section 12–513
27 Annotated Code of Maryland
28 (2014 Replacement Volume and 2020 Supplement)

29 BY adding to

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 Article – Health – General
2 Section 15–102.3(j) and 15–103(a)(2)(xvii)
3 Annotated Code of Maryland
4 (2019 Replacement Volume and 2020 Supplement)

5 BY repealing and reenacting, without amendments,
6 Article – Health – General
7 Section 15–103(a)(1)
8 Annotated Code of Maryland
9 (2019 Replacement Volume and 2020 Supplement)

10 BY repealing and reenacting, with amendments,
11 Article – Health – General
12 Section 15–103(a)(2)(xv) and (xvi)
13 Annotated Code of Maryland
14 (2019 Replacement Volume and 2020 Supplement)

15 BY adding to
16 Article – Insurance
17 Section 15–856
18 Annotated Code of Maryland
19 (2017 Replacement Volume and 2020 Supplement)

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

22 **Article – Health Occupations**

23 **12–513.**

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

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

31 **(3) “CDC GUIDELINES FOR PREEXPOSURE PROPHYLAXIS” MEANS**
32 **“PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE**
33 **UNITED STATES–2017 UPDATE: A CLINICAL PRACTICE GUIDELINE” OR ANY**
34 **SUBSEQUENT GUIDELINES, PUBLISHED BY THE FEDERAL CENTERS FOR DISEASE**
35 **CONTROL AND PREVENTION.**

1 **(4) “POSTEXPOSURE PROPHYLAXIS” MEANS ANY DRUG**
2 **COMBINATION USED TO PREVENT HIV INFECTION FOLLOWING AN EXPOSURE OR**
3 **POTENTIAL EXPOSURE TO HIV AS DEFINED BY:**

4 **(I) THE BOARD OF NURSING;**

5 **(II) THE BOARD OF PHARMACY;**

6 **(III) THE BOARD OF PHYSICIANS; OR**

7 **(IV) THE CDC, IN THE CDC GUIDELINES FOR POSTEXPOSURE**
8 **PROPHYLAXIS.**

9 **(5) “PREEXPOSURE PROPHYLAXIS” MEANS ANY DRUG COMBINATION**
10 **PROVIDED TO AN HIV-NEGATIVE PERSON TO PREVENT HIV INFECTION AS DEFINED**
11 **BY:**

12 **(I) THE BOARD OF NURSING;**

13 **(II) THE BOARD OF PHARMACY;**

14 **(III) THE BOARD OF PHYSICIANS; OR**

15 **(IV) THE CDC, IN THE CDC GUIDELINES FOR PREEXPOSURE**
16 **PROPHYLAXIS.**

17 **(B) (1) A PHARMACIST MAY DISPENSE A 30-DAY SUPPLY, BUT NOT MORE**
18 **THAN A 60-DAY SUPPLY, OF PREEXPOSURE PROPHYLAXIS TO A PATIENT WITHOUT A**
19 **PRESCRIPTION IF:**

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

22 **(II) THE PATIENT COMPLETES A SELF-SCREENING**
23 **ASSESSMENT TOOL AND REPORTS:**

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

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

27 **(III) AT THE TIME THE PREEXPOSURE PROPHYLAXIS IS**
28 **DISPENSED, THE PHARMACIST PROVIDES:**

1 1. **COUNSELING TO THE PATIENT ON THE ONGOING USE**
2 **OF PREEXPOSURE PROPHYLAXIS, INCLUDING EDUCATION REGARDING SIDE**
3 **EFFECTS, SAFETY DURING PREGNANCY AND BREASTFEEDING, ADHERENCE TO**
4 **RECOMMENDED DOSING, AND THE IMPORTANCE OF TIMELY TESTING AND**
5 **TREATMENT, AS APPLICABLE, FOR:**

6 A. **HIV;**

7 B. **RENAL FUNCTION;**

8 C. **HEPATITIS B;**

9 D. **HEPATITIS C;**

10 E. **SEXUALLY TRANSMITTED DISEASES;**

11 F. **PREGNANCY FOR INDIVIDUALS OF CHILDBEARING**
12 **CAPACITY; AND**

13 2. **ORAL AND WRITTEN NOTICE TO THE PATIENT THAT:**

14 A. **THE PATIENT MUST BE SEEN BY A HEALTH CARE**
15 **PROVIDER TO RECEIVE A PRESCRIPTION FOR PREEXPOSURE PROPHYLAXIS; AND**

16 B. **A PHARMACIST MAY NOT DISPENSE A COMBINED**
17 **60-DAY SUPPLY OF PREEXPOSURE PROPHYLAXIS TO A SINGLE PATIENT MORE THAN**
18 **ONCE EVERY 2 YEARS;**

19 (IV) **THE PHARMACIST RECORDS THE DISPENSING OF THE**
20 **PREEXPOSURE PROPHYLAXIS IN ANY ELECTRONIC HEALTH RECORD MAINTAINED**
21 **ON THE PATIENT BY THE PHARMACIST;**

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

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

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

1 **2. IF THE PATIENT DOES NOT HAVE A PRIMARY CARE**
2 **PROVIDER OR REFUSES TO PROVIDE THE NAME OF A PRIMARY CARE PROVIDER, THE**
3 **PATIENT WITH A LIST OF PHYSICIANS, CLINICS, OR OTHER HEALTH CARE**
4 **PROVIDERS TO CONTACT REGARDING ONGOING CARE FOR PREEXPOSURE**
5 **PROPHYLAXIS.**

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

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

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

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

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

21 **1. THE TEST RESULTS ARE NOT TRANSMITTED**
22 **DIRECTLY TO THE PHARMACIST, THE PHARMACIST SHALL VERIFY THE TEST**
23 **RESULTS TO THE PHARMACIST'S SATISFACTION; OR**

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

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

31 **(I) SCREENS THE PATIENT AND DETERMINES:**

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

3 2. THE PATIENT OTHERWISE MEETS THE CLINICAL
4 CRITERIA FOR POSTEXPOSURE PROPHYLAXIS CONSISTENT WITH THE CDC
5 GUIDELINES FOR POSTEXPOSURE PROPHYLAXIS;

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

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

12 (iii) PROVIDES COUNSELING TO THE PATIENT ON:

13 1. THE USE OF POSTEXPOSURE PROPHYLAXIS
14 CONSISTENT WITH THE CDC GUIDELINES FOR POSTEXPOSURE PROPHYLAXIS,
15 INCLUDING EDUCATION REGARDING SIDE EFFECTS, SAFETY DURING PREGNANCY
16 AND BREASTFEEDING, ADHERENCE TO RECOMMENDED DOSING, AND THE
17 IMPORTANCE OF TIMELY TESTING AND TREATMENT, AS APPLICABLE, FOR HIV AND
18 SEXUALLY TRANSMITTED DISEASES; AND

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

21 (iv) PROVIDES:

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

24 2. IF THE PATIENT DOES NOT HAVE A PRIMARY CARE
25 PROVIDER OR REFUSES TO PROVIDE THE NAME OF A HEALTH CARE PROVIDER, THE
26 PATIENT WITH A LIST OF PHYSICIANS, CLINICS, OR OTHER HEALTH CARE
27 PROVIDERS TO CONTACT REGARDING FOLLOW-UP CARE FOR POSTEXPOSURE
28 PROPHYLAXIS.

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

31 (3) IF THE PATIENT REFUSES TO CONSENT TO AN HIV TEST UNDER
32 PARAGRAPH (1)(ii)2 OF THIS SUBSECTION BUT OTHERWISE MEETS THE CRITERIA

1 FOR POSTEXPOSURE PROPHYLAXIS UNDER THIS SUBSECTION, THE PHARMACIST
2 MAY DISPENSE POSTEXPOSURE PROPHYLAXIS TO THE PATIENT.

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

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

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

15 Article – Health – General

16 15–103.

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

19 (2) The Program:

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

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

31 (XVII) SHALL PROVIDE, SUBJECT TO THE LIMITATIONS OF THE
32 STATE BUDGET, MEDICALLY APPROPRIATE DRUGS THAT ARE APPROVED BY THE
33 UNITED STATES FOOD AND DRUG ADMINISTRATION FOR HIV PREVENTION,
34 INCLUDING:

1 **1. PREEXPOSURE PROPHYLAXIS, LIMITED TO A 60-DAY**
2 **SUPPLY WITHOUT A PRESCRIPTION; AND**

3 **2. POSTEXPOSURE PROPHYLAXIS, AS DEFINED IN §**
4 **12-513 OF THE HEALTH OCCUPATIONS ARTICLE.**

5 SECTION 2. AND BE IT FURTHER ENACTED, That the Laws of Maryland read
6 as follows:

7 **Article – Health – General**

8 15-102.3.

9 **(J) THE PROVISIONS OF § 15-856 OF THE INSURANCE ARTICLE APPLY TO**
10 **MANAGED CARE ORGANIZATIONS IN THE SAME MANNER AS THEY APPLY TO**
11 **CARRIERS.**

12 **Article – Insurance**

13 **15-856.**

14 **(A) THIS SECTION APPLIES TO:**

15 **(1) 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 **(2) 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 **(B) AN ENTITY SUBJECT TO THIS SECTION MAY NOT REQUIRE PRIOR**
23 **AUTHORIZATION FOR:**

24 **(1) PREEXPOSURE PROPHYLAXIS FOR HIV PREVENTION DISPENSED**
25 **WITH A PRESCRIPTION;**

26 **(2) UP TO A 60-DAY SUPPLY OF A PREEXPOSURE PROPHYLAXIS FOR**
27 **HIV PREVENTION DISPENSED WITHOUT A PRESCRIPTION; OR**

28 **(3) POSTEXPOSURE PROPHYLAXIS FOR HIV PREVENTION.**

1 **(C) AN ENTITY SUBJECT TO THIS SECTION MAY NOT IMPOSE ANY**
2 **COST-SHARING REQUIREMENTS, INCLUDING COPAYMENTS, COINSURANCE, OR**
3 **DEDUCTIBLES, FOR MEDICALLY NECESSARY AND APPROPRIATE SERVICES RELATED**
4 **TO THE USE OF POSTEXPOSURE PROPHYLAXIS OR PREEXPOSURE PROPHYLAXIS,**
5 **INCLUDING:**

6 **(1) HIV TESTING;**

7 **(2) KIDNEY FUNCTION TESTING;**

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

9 **(4) PREGNANCY TESTING;**

10 **(5) PROVIDER OFFICE AND TELEHEALTH VISITS FOR PRESCRIBING**
11 **AND MEDICATION MANAGEMENT;**

12 **(6) SEROLOGIC LABORATORY TESTING FOR HEPATITIS B AND**
13 **HEPATITIS C VIRUSES;**

14 **(7) TESTING FOR OTHER SEXUALLY TRANSMITTED INFECTIONS,**
15 **INCLUDING 3-SITE TESTING FOR GONORRHEA AND CHLAMYDIA; AND**

16 **(8) VACCINATIONS FOR HEPATITIS B.**

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

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

22 SECTION 5. AND BE IT FURTHER ENACTED, That, except as provided in Section
23 4 of this Act, this Act shall take effect October 1, 2021.