

SENATE BILL 64

J2, J5, J4

3lr0314

SB 355/22 – EHE & FIN

(PRE-FILED)

By: **Senator Lam**

Requested: July 6, 2022

Introduced and read first time: January 11, 2023

Assigned to: 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 postexposure
5 prophylaxis for HIV prevention to patients under certain circumstances; requiring
6 the Maryland Medical Assistance Program to provide drugs that are approved by the
7 U.S. Food and Drug Administration for HIV prevention; prohibiting managed care
8 organizations, insurers, nonprofit health service plans, and health maintenance
9 organizations from requiring prior authorization for preexposure prophylaxis for
10 HIV prevention or 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 adding to

14 Article – Health – General
15 Section 15–102.3(k) and 15–103(a)(2)(xxii)
16 Annotated Code of Maryland
17 (2019 Replacement Volume and 2022 Supplement)

18 BY repealing and reenacting, without amendments,

19 Article – Health – General
20 Section 15–103(a)(1)
21 Annotated Code of Maryland
22 (2019 Replacement Volume and 2022 Supplement)

23 BY repealing and reenacting, with amendments,

24 Article – Health – General
25 Section 15–103(a)(2)(xx) and (xxi) and (b)(32)
26 Annotated Code of Maryland
27 (2019 Replacement Volume and 2022 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 Occupations
3 Section 12–101(x)(1)(xii) and (xiii)
4 Annotated Code of Maryland
5 (2021 Replacement Volume and 2022 Supplement)

6 BY adding to
7 Article – Health Occupations
8 Section 12–101(x)(1)(xiv) and 12–515
9 Annotated Code of Maryland
10 (2021 Replacement Volume and 2022 Supplement)

11 BY repealing and reenacting, with amendments,
12 Article – Insurance
13 Section 15–858
14 Annotated Code of Maryland
15 (2017 Replacement Volume and 2022 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 – General**

19 15–103.

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

22 (2) The Program:

23 (xx) Beginning on July 1, 2023, shall provide, subject to federal
24 approval and limitations of the State budget, community violence prevention services in
25 accordance with § 15–141.3 of this subtitle; [and]

26 (xxi) Beginning on January 1, 2023, shall provide, subject to the
27 limitations of the State budget, and as permitted by federal law, coverage for self-measured
28 blood pressure monitoring for all Program recipients diagnosed with uncontrolled high
29 blood pressure, including:

30 1. The provision of validated home blood pressure monitors;
31 and

32 2. Reimbursement of health care provider and other staff
33 time used for patient training, transmission of blood pressure data, interpretation of blood
34 pressure readings and reporting, and the delivery of co-interventions, including
35 educational materials or classes, behavioral change management, and medication

1 management; AND

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

5 1. PREEXPOSURE PROPHYLAXIS; AND

6 2. POSTEXPOSURE PROPHYLAXIS, AS DEFINED IN §
7 12-515 OF THE HEALTH OCCUPATIONS ARTICLE.

8 (b) (32) A managed care organization may not apply a prior authorization
9 requirement for a prescription drug used as **PREEXPOSURE PROPHYLAXIS OR**
10 **postexposure prophylaxis** for the prevention of HIV if the prescription drug is prescribed
11 for use in accordance with Centers for Disease Control and Prevention Guidelines.

12 **Article – Health Occupations**

13 12-101.

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

15 (ii) Prescribing and dispensing contraceptive medications and
16 self-administered contraceptive devices approved by the U.S. Food and Drug
17 Administration; [or]

18 (iii) Prescribing and dispensing nicotine replacement therapy
19 medications; OR

20 (XIV) **PRESCRIBING AND DISPENSING POSTEXPOSURE**
21 **PROPHYLAXIS MEDICATIONS FOR HIV APPROVED BY THE U.S. FOOD AND DRUG**
22 **ADMINISTRATION.**

23 12-515.

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**

1 **“PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE**
2 **UNITED STATES – 2017 UPDATE: A CLINICAL PRACTICE GUIDELINE” OR ANY**
3 **SUBSEQUENT GUIDELINES PUBLISHED BY THE FEDERAL CENTERS FOR DISEASE**
4 **CONTROL AND PREVENTION.**

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

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

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

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

13 (I) **PROVIDED TO AN HIV–NEGATIVE PERSON TO PREVENT**
14 **HIV INFECTION; AND**

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

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

22 (B) (1) **A PHARMACIST MAY PRESCRIBE AND DISPENSE A COMPLETE**
23 **COURSE OF POSTEXPOSURE PROPHYLAXIS TO A PATIENT IF THE PHARMACIST:**

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

25 1. **THE EXPOSURE TO HIV OCCURRED WITHIN THE**
26 **IMMEDIATELY PRECEDING 72 HOURS; AND**

27 2. **THE PATIENT OTHERWISE MEETS THE CLINICAL**
28 **CRITERIA FOR POSTEXPOSURE PROPHYLAXIS CONSISTENT WITH THE CDC**
29 **GUIDELINES FOR POSTEXPOSURE PROPHYLAXIS;**

30 (II) 1. **PROVIDES HIV TESTING THAT IS CLASSIFIED AS**
31 **WAIVED UNDER THE FEDERAL CLINICAL LABORATORY IMPROVEMENT**
32 **AMENDMENTS OF 1988; OR**

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

4 **(III) PROVIDES COUNSELING TO THE PATIENT ON:**

5 **1. THE USE OF POSTEXPOSURE PROPHYLAXIS**
6 **CONSISTENT WITH THE CDC GUIDELINES FOR POSTEXPOSURE PROPHYLAXIS,**
7 **INCLUDING EDUCATION REGARDING SIDE EFFECTS, SAFETY DURING PREGNANCY**
8 **AND BREASTFEEDING, ADHERENCE TO RECOMMENDED DOSING, AND THE**
9 **IMPORTANCE OF TIMELY TESTING AND TREATMENT, AS APPLICABLE, FOR HIV AND**
10 **SEXUALLY TRANSMITTED DISEASES; AND**

11 **2. THE AVAILABILITY OF PREEXPOSURE PROPHYLAXIS**
12 **FOR INDIVIDUALS WHO ARE AT SUBSTANTIAL RISK OF CONTRACTING HIV; AND**

13 **(IV) PROVIDES:**

14 **1. NOTICE TO THE PATIENT'S PRIMARY CARE PROVIDER**
15 **OF THE POSTEXPOSURE PROPHYLAXIS TREATMENT; OR**

16 **2. IF THE PATIENT DOES NOT HAVE A PRIMARY CARE**
17 **PROVIDER OR REFUSES TO PROVIDE THE NAME OF A HEALTH CARE PROVIDER, THE**
18 **PATIENT WITH A LIST OF PHYSICIANS, CLINICS, OR OTHER HEALTH CARE**
19 **PROVIDERS IN THE AREA, INCLUDING PROVIDERS THAT RECEIVE FUNDING, EITHER**
20 **DIRECTLY OR INDIRECTLY, FROM THE RYAN WHITE HIV/AIDS PROGRAM, TO**
21 **CONTACT REGARDING FOLLOW-UP CARE FOR POSTEXPOSURE PROPHYLAXIS.**

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

24 **(3) IF THE PATIENT REFUSES TO CONSENT TO AN HIV TEST UNDER**
25 **PARAGRAPH (1)(II)2 OF THIS SUBSECTION BUT OTHERWISE MEETS THE CRITERIA**
26 **FOR POSTEXPOSURE PROPHYLAXIS UNDER THIS SUBSECTION, THE PHARMACIST**
27 **MAY PRESCRIBE AND DISPENSE POSTEXPOSURE PROPHYLAXIS TO THE PATIENT.**

28 **(C) (1) (I) BEFORE PRESCRIBING AND DISPENSING POSTEXPOSURE**
29 **PROPHYLAXIS TO A PATIENT, A PHARMACIST SHALL COMPLETE A TRAINING**
30 **PROGRAM ON THE AVAILABILITY OF PREEXPOSURE PROPHYLAXIS AND ON THE USE**
31 **OF POSTEXPOSURE PROPHYLAXIS THAT IS APPROVED BY THE BOARD.**

32 **(II) THE TRAINING PROGRAM REQUIRED UNDER**
33 **SUBPARAGRAPH (I) OF THIS PARAGRAPH SHALL INCLUDE INFORMATION ABOUT**

1 FINANCIAL ASSISTANCE PROGRAMS FOR PREEXPOSURE PROPHYLAXIS AND
2 POSTEXPOSURE PROPHYLAXIS.

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

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

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

15 **Article – Health – General**

16 15–102.3.

17 (K) THE PROVISIONS OF § 15–858 OF THE INSURANCE ARTICLE APPLY TO
18 MANAGED CARE ORGANIZATIONS IN THE SAME MANNER AS THEY APPLY TO
19 CARRIERS.

20 **Article – Insurance**

21 15–858.

22 (a) (1) [This] EXCEPT AS PROVIDED IN PARAGRAPH (3) OF THIS
23 SUBSECTION, THIS section applies to:

24 (i) insurers and nonprofit health service plans that provide coverage
25 for prescription drugs under individual, group, or blanket health insurance policies or
26 contracts that are issued or delivered in the State; and

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

30 (2) An insurer, a nonprofit health service plan, or a health maintenance
31 organization that provides coverage for prescription drugs through a pharmacy benefits
32 manager is subject to the requirements of this section.

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

3 (b) An entity subject to this section may not apply a prior authorization
4 requirement **OR STEP THERAPY OR IMPOSE ANY COST-SHARING REQUIREMENTS,**
5 **INCLUDING COPAYMENTS, COINSURANCE, OR DEDUCTIBLES,** for a prescription drug
6 used as **PREEXPOSURE PROPHYLAXIS OR** postexposure prophylaxis for the prevention of
7 HIV if the prescription drug is prescribed for use in accordance with Centers for Disease
8 Control and Prevention guidelines.

9 **(C) AN ENTITY SUBJECT TO THIS SECTION MAY NOT IMPOSE ANY**
10 **COST-SHARING REQUIREMENTS, INCLUDING COPAYMENTS, COINSURANCE, OR**
11 **DEDUCTIBLES, FOR MEDICALLY NECESSARY AND APPROPRIATE SERVICES RELATED**
12 **TO THE USE OF PREEXPOSURE PROPHYLAXIS OR POSTEXPOSURE PROPHYLAXIS,**
13 **INCLUDING:**

14 **(1) HIV TESTING;**

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

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

17 **(4) PREGNANCY TESTING;**

18 **(5) PROVIDER OFFICE AND TELEHEALTH VISITS FOR PRESCRIBING**
19 **AND MEDICATION MANAGEMENT;**

20 **(6) SEROLOGIC LABORATORY TESTING FOR HEPATITIS B AND**
21 **HEPATITIS C VIRUSES;**

22 **(7) TESTING FOR OTHER SEXUALLY TRANSMITTED INFECTIONS,**
23 **INCLUDING THREE-SITE TESTING FOR GONORRHEA AND CHLAMYDIA; AND**

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

25 SECTION 3. AND BE IT FURTHER ENACTED, That Section 2 of this Act shall
26 apply to all policies, contracts, and health benefit plans that are not grandfathered plans
27 as defined in § 1251 of the Affordable Care Act issued, delivered, or renewed in the State
28 on or after January 1, 2024.

29 SECTION 4. AND BE IT FURTHER ENACTED, That Section 2 of this Act shall take
30 effect January 1, 2024.

31 SECTION 5. AND BE IT FURTHER ENACTED, That, except as provided in Section
32 4 of this Act, this Act shall take effect October 1, 2023.