HOUSE BILL 127

J1, J2 4lr0194 (PRE-FILED) CF SB 246 By: Chair, Health and Government Operations Committee (By Request -Departmental - Health) Requested: September 13, 2023 Introduced and read first time: January 10, 2024 Assigned to: Health and Government Operations A BILL ENTITLED AN ACT concerning Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment FOR the purpose of establishing the Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program to authorize pharmacists and health care providers to prescribe or dispense nPEP under certain circumstances; authorizing the Maryland Department of Health to administer the Program, collect fees necessary for the administration of the Program, and establish guidelines for training related to the Program; and generally relating to the Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program. BY adding to Article – Health – General Section 13-5201 through 13-5205 to be under the new subtitle "Subtitle 52. Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program"

17 BY repealing and reenacting, without amendments,

Annotated Code of Maryland (2023 Replacement Volume)

18 Article – Health Occupations

19 Section 12–101(a)

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20 Annotated Code of Maryland

21 (2021 Replacement Volume and 2023 Supplement)

22 BY repealing and reenacting, with amendments,

23 Article – Health Occupations

24 Section 12–101(x)

25 Annotated Code of Maryland

26 (2021 Replacement Volume and 2023 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



- 1 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
- 2 That the Laws of Maryland read as follows:
- 3 Article Health General
- 4 SUBTITLE 52. NONOCCUPATIONAL POSTEXPOSURE PROPHYLAXIS (NPEP)
- 5 STANDING ORDER PROGRAM.
- 6 **13–5201**.
- 7 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
- 8 INDICATED.
- 9 (B) "BOARD" MEANS THE STATE BOARD OF PHARMACY.
- 10 (C) "CDC GUIDELINES" MEANS THE "UPDATED GUIDELINES FOR
- 11 ANTIRETROVIRAL POSTEXPOSURE PROPHYLAXIS AFTER SEXUAL, INJECTION
- 12 DRUG USE, OR OTHER NONOCCUPATIONAL EXPOSURE TO HIV UNITED STATES
- 13 2016" OR ANY SUBSEQUENT GUIDELINES PUBLISHED BY THE CENTERS FOR
- 14 DISEASE CONTROL AND PREVENTION.
- 15 (D) "NONOCCUPATIONAL POSTEXPOSURE PROPHYLAXIS" OR "NPEP"
- 16 MEANS MEDICATION USED IN ACCORDANCE WITH CDC GUIDELINES TO REDUCE
- 17 THE CHANCES OF A PATIENT DEVELOPING HIV AFTER POTENTIAL EXPOSURE TO
- 18 THE DISEASE.
- 19 (E) "PHARMACIST" MEANS A PHARMACIST LICENSED IN THE STATE UNDER
- 20 TITLE 12 OF THE HEALTH OCCUPATIONS ARTICLE.
- 21 (F) "PRIVATE OR PUBLIC ENTITY" MEANS A HEALTH CARE PROVIDER,
- 22 LOCAL HEALTH DEPARTMENT, COMMUNITY-BASED ORGANIZATION, OR OTHER
- 23 PERSON THAT ADDRESSES MEDICAL OR SOCIAL ISSUES RELATED TO HIV
- 24 EXPOSURE.
- 25 (G) "PROGRAM" MEANS THE NONOCCUPATIONAL POSTEXPOSURE
- 26 PROPHYLAXIS (NPEP) STANDING ORDER PROGRAM.
- 27 (H) "STANDING ORDER" MEANS A DIRECTIVE AUTHORIZING PHARMACISTS
- 28 AND HEALTH CARE PROVIDERS TO DISPENSE THE NPEP REGIMENS LISTED IN THE
- 29 ORDER WITHOUT A PRESCRIPTION.
- 30 **13-5202**.

- (A) THERE IS A NONOCCUPATIONAL POSTEXPOSURE PROPHYLAXIS 1 (NPEP) STANDING ORDER PROGRAM. THE PROGRAM SHALL: 3 (B) 4 **(1)** AUTHORIZE A PHARMACIST WHO IS REGISTERED WITH THE 5 PROGRAM TO DISPENSE NPEP THROUGH A STANDING ORDER IN ACCORDANCE 6 WITH § 13–5203 OF THIS SUBTITLE; 7 **(2)** AUTHORIZE A LICENSED HEALTH CARE PROVIDER WITH 8 PRESCRIBING AUTHORITY TO PRESCRIBE AND DISPENSE NPEP THROUGH A STANDING ORDER IN ACCORDANCE WITH § 13-5204 OF THIS SUBTITLE; AND 9 10 OPERATE IN ACCORDANCE WITH THE PROCEDURES APPROVED BY **(3)** 11 THE DEPARTMENT WITH THE ADVICE AND APPROVAL OF THE BOARD. THE DEPARTMENT SHALL ADOPT REGULATIONS NECESSARY FOR THE 12 (C) 13 ADMINISTRATION OF THE PROGRAM. 14 (D) THE DEPARTMENT MAY: 15 **(1)** COLLECT FEES NECESSARY FOR THE ADMINISTRATION OF THE PROGRAM; 16 ADMINISTER THE PROGRAM AND ESTABLISH A STANDARDIZED 17 SET OF GUIDELINES FOR PRIVATE AND PUBLIC ENTITIES PARTICIPATING IN THE 18 19 PROGRAM TO USE IN DEVELOPING AND CONDUCTING PATIENT EDUCATION AND 20 TRAINING ON NPEP THAT INCLUDES: AVOIDING EXPOSURE TO HIV; 21(I)22 HIV (II)RESPONDING TO EXPOSURE TO WITH THE APPROPRIATE USE OF NPEP: 23
- 27 1. ACCESS TO PRE-EXPOSURE PROPHYLAXIS (PREP); 28 AND

AFTER THE ADMINISTRATION OF NPEP; AND

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(III) ACCESS TO NPEP AND THE APPROPRIATE FOLLOW-UP

ENGAGEMENT IN ADDITIONAL CARE INCLUDING:

- 1 2. HARM REDUCTION PROGRAMS FOR PATIENTS WITH 2 CONTINUING RISK OF EXPOSURES; AND
- 3 (3) COLLECT AND REPORT DATA ON THE OPERATION AND RESULTS 4 OF THE PROGRAM.
- 5 **13–5203.**
- 6 (A) AT THE TIME OF DISPENSING NPEP, A PHARMACIST REGISTERED WITH 7 THE PROGRAM SHALL:
- 8 (1) SCREEN THE PATIENT TO DETERMINE THAT HIV EXPOSURE 9 OCCURRED WITHIN 72 HOURS BEFORE THE DISPENSING;
- 10 (2) DETERMINE WHETHER THE PATIENT MEETS CLINICAL CRITERIA 11 CONSISTENT WITH CDC GUIDELINES, INCLUDING THE IDENTIFICATION OF ANY 12 CONTRAINDICATED MEDICATIONS;
- 13 (3) SUBJECT TO SUBSECTION (B) OF THIS SECTION, DETERMINE
 14 WHETHER AN AVAILABLE STANDING ORDER IS APPROPRIATE FOR THE PATIENT AND
 15 DISPENSE NPEP IN ACCORDANCE WITH CDC GUIDELINES;
- 16 (4) REFER THE PATIENT TO A DISEASE INTERVENTION SPECIALIST WITHIN THE DEPARTMENT FOR ONGOING TREATMENT; AND
- 18 **(5) DETERMINE WHETHER THE PATIENT HAS A PRIMARY CARE** 19 **PROVIDER AND:**
- 20 (I) IF THE PATIENT HAS A PRIMARY CARE PROVIDER, NOTIFY 21 THE PROVIDER THAT THE PATIENT WAS DISPENSED NPEP; OR
- 22 (II) IF THE PATIENT DOES NOT HAVE A PRIMARY CARE 23 PROVIDER, PROVIDE THE PATIENT WITH A LIST OF PRIMARY CARE PROVIDERS AND 24 CLINICS.
- 25 (B) IF AN AVAILABLE STANDING ORDER IS NOT APPROPRIATE FOR THE 26 PATIENT, THE PHARMACIST SHALL REFER THE PATIENT TO A PRIMARY CARE 27 PROVIDER.
- 28 (C) A PHARMACIST MAY DISPENSE NPEP IN ACCORDANCE WITH A THERAPY
 29 MANAGEMENT CONTRACT UNDER TITLE 12, SUBTITLE 6A OF THE HEALTH
 30 OCCUPATIONS ARTICLE.

1 **13–5204.**

- 2 (A) A LICENSED HEALTH CARE PROVIDER WITH PRESCRIBING AUTHORITY 3 WHO IS REGISTERED WITH THE PROGRAM MAY DELEGATE THE DISPENSING OF
- 4 NPEP UNDER A STANDING ORDER TO AN EMPLOYEE OR A VOLUNTEER OF AN
- 5 AUTHORIZED PRIVATE OR PUBLIC ENTITY IN ACCORDANCE WITH A WRITTEN
- 6 AGREEMENT UNDER § 13–5205 OF THIS SUBTITLE.
- 7 (B) ANY LICENSED HEALTH CARE PROVIDER WHO HAS DISPENSING
- 8 AUTHORITY MAY DISPENSE NPEP TO AN INDIVIDUAL IN ACCORDANCE WITH A
- 9 STANDING ORDER IN ACCORDANCE WITH THIS SUBSECTION.
- 10 **13–5205.**
- AN AUTHORIZED PRIVATE OR PUBLIC ENTITY SHALL ENTER INTO A WRITTEN
- 12 AGREEMENT WITH A LICENSED HEALTH CARE PROVIDER WITH PRESCRIBING
- 13 AUTHORITY TO ESTABLISH PROTOCOLS FOR THE PRESCRIBING AND DISPENSING OF
- 14 NPEP TO ANY INDIVIDUAL IN ACCORDANCE WITH THIS SUBTITLE.

15 Article - Health Occupations

- 16 12–101.
- 17 (a) In this title the following words have the meanings indicated.
- 18 (x) (1) "Practice pharmacy" means to engage in any of the following activities:
- 19 (i) Providing pharmaceutical care;
- 20 (ii) Compounding, dispensing, or distributing prescription drugs or
- 21 devices;
- 22 (iii) Compounding or dispensing nonprescription drugs or devices;
- 23 (iv) Monitoring prescriptions for prescription and nonprescription
- 24 drugs or devices;
- 25 (v) Providing information, explanation, or recommendations to
- 26 patients and health care practitioners about the safe and effective use of prescription or
- 27 nonprescription drugs or devices;
- 28 (vi) Identifying and appraising problems concerning the use or
- 29 monitoring of therapy with drugs or devices;

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PREVENTION.

- 1 (vii) Acting within the parameters of a therapy management contract, 2 as provided under Subtitle 6A of this title;
- 3 (viii) Administering vaccinations in accordance with § 12–508 of this 4 title or self-administered drugs or maintenance injectable medications in accordance with § 12–509 of this title;
- 6 (ix) Delegating a pharmacy act to a registered pharmacy technician, 7 pharmacy student, or an individual engaged in a Board approved pharmacy technician 8 training program;
- 9 (x) Supervising a delegated pharmacy act performed by a registered 10 pharmacy technician, pharmacy student, or an individual engaged in a Board approved 11 pharmacy technician training program;
- 12 (xi) Providing drug therapy management in accordance with § 13 19–713.6 of the Health General Article;
- (xii) Prescribing and dispensing contraceptive medications and self-administered contraceptive devices approved by the U.S. Food and Drug Administration; [or]
- 17 (xiii) Prescribing and dispensing nicotine replacement therapy 18 medications; OR
- 19 (XIV) IF THE PHARMACIST \mathbf{IS} REGISTERED WITH THE 20 NONOCCUPATIONAL POSTEXPOSURE PROPHYLAXIS (NPEP) STANDING ORDER 21PROGRAM ESTABLISHED UNDER § 13-5202 OF THE HEALTH - GENERAL ARTICLE, 22PRESCRIBING AND DISPENSING NONOCCUPATIONAL POSTEXPOSURE PROPHYLAXIS (NPEP) MEDICATION APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION 23AND IN ACCORDANCE WITH "UPDATED GUIDELINES FOR ANTIRETROVIRAL 24POSTEXPOSURE PROPHYLAXIS AFTER SEXUAL, INJECTION DRUG USE, OR OTHER 25NONOCCUPATIONAL EXPOSURE TO HIV - UNITED STATES 2016" OR SUBSEQUENT 26 27 GUIDELINES PUBLISHED BY THE FEDERAL CENTERS FOR DISEASE CONTROL AND
- 29 (2) "Practice pharmacy" does not include the operations of a person who 30 holds a permit issued under $\S 12-6C-03$ of this title.
- 31 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 32 October 1, 2024.