HOUSE BILL 127

J1, J2	(PRE-	FILED)			4lr0194 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								
Committee Report: Favorable with amendments								
House action: Adopted								
Read second time: February 23, 2024								

CHAPTER _____

1 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.
- 11 BY adding to
- 12 Article Health General
- Section 13–5201 through 13–5205 <u>13–5203</u> to be under the new subtitle "Subtitle 52.
 Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program"
- 15 Annotated Code of Maryland
- 16 (2023 Replacement Volume)
- 17 BY repealing and reenacting, without amendments,
- 18 Article Health Occupations
- 19 Section 12–101(a)
- 20 Annotated Code of Maryland
- 21 (2021 Replacement Volume and 2023 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

<u>Underlining</u> indicates amendments to bill.

Strike out indicates matter stricken from the bill by amendment or deleted from the law by amendment.



- 1 BY repealing and reenacting, with amendments,
- 2 Article Health Occupations
- 3 Section 12–101(x)
- 4 Annotated Code of Maryland
- 5 (2021 Replacement Volume and 2023 Supplement)
- 6 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
 7 That the Laws of Maryland read as follows:
- 8 Article Health General
 9 SUBTITLE 52. NONOCCUPATIONAL POSTEXPOSURE PROPHYLAXIS (NPEP)
 10 STANDING ORDER PROGRAM.
- 11 **13–5201.**

12 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS 13 INDICATED.

14 (B) "BOARD" MEANS THE STATE BOARD OF PHARMACY.

15 (C) "CDC GUIDELINES" MEANS THE "UPDATED GUIDELINES FOR 16 ANTIRETROVIRAL POSTEXPOSURE PROPHYLAXIS AFTER SEXUAL, INJECTION 17 DRUG USE, OR OTHER NONOCCUPATIONAL EXPOSURE TO HIV – UNITED STATES 18 2016" OR ANY SUBSEQUENT GUIDELINES PUBLISHED BY THE CENTERS FOR 19 DISEASE CONTROL AND PREVENTION.

20 (D) "NONOCCUPATIONAL POSTEXPOSURE PROPHYLAXIS" OR "NPEP" 21 MEANS MEDICATION USED IN ACCORDANCE WITH <u>THE MOST RECENT</u> CDC 22 GUIDELINES TO REDUCE THE CHANCES OF A PATIENT DEVELOPING HIV AFTER 23 POTENTIAL EXPOSURE TO THE DISEASE.

24 (E) "PHARMACIST" MEANS A PHARMACIST LICENSED IN THE STATE UNDER 25 TITLE 12 OF THE HEALTH OCCUPATIONS ARTICLE.

26 (F) "PRIVATE OR PUBLIC ENTITY" MEANS A HEALTH CARE PROVIDER, 27 LOCAL HEALTH DEPARTMENT, COMMUNITY-BASED ORGANIZATION, OR OTHER 28 PERSON THAT ADDRESSES MEDICAL OR SOCIAL ISSUES RELATED TO HIV 29 EXPOSURE.

30 (G) (F) "PROGRAM" MEANS THE NONOCCUPATIONAL POSTEXPOSURE 31 PROPHYLAXIS (NPEP) STANDING ORDER PROGRAM.

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1 (H) (G) "STANDING ORDER" MEANS A DIRECTIVE AUTHORIZING 2 PHARMACISTS AND HEALTH CARE PROVIDERS TO DISPENSE THE NPEP REGIMENS 3 LISTED IN THE ORDER WITHOUT A PRESCRIPTION.

4 **13–5202.**

5 (A) THERE IS A NONOCCUPATIONAL POSTEXPOSURE PROPHYLAXIS 6 (NPEP) STANDING ORDER PROGRAM.

7 (B) THE PROGRAM SHALL:

8 (1) AUTHORIZE A PHARMACIST WHO IS REGISTERED WITH THE 9 PROGRAM TO DISPENSE NPEP THROUGH A STANDING ORDER IN ACCORDANCE 10 WITH § 13–5203 OF THIS SUBTITLE; <u>AND</u>

11(2)Authorize A licensed health care provider with12PRESCRIBING AUTHORITY TO PRESCRIBE AND DISPENSE NPEP THROUGH A13STANDING ORDER IN ACCORDANCE WITH § 13–5204 OF THIS SUBTITLE; AND

14 (3) OPERATE IN ACCORDANCE WITH THE PROCEDURES APPROVED BY
 15 THE DEPARTMENT WITH THE ADVICE AND APPROVAL OF THE BOARD.

- 16 (C) THE DEPARTMENT SHALL ADOPT REGULATIONS <u>NECESSARY:</u>
- 17 (1) <u>NECESSARY</u> FOR THE ADMINISTRATION OF THE PROGRAM; AND

18(2)THAT ADDRESS THE NEEDS OF SPECIFIC POPULATIONS19INCLUDING VICTIMS OF SEXUAL ASSAULT AND PEDIATRIC PATIENTS.

20 (D) THE DEPARTMENT MAY:

(1) COLLECT FEES NECESSARY FOR THE ADMINISTRATION OF THE
 PROGRAM, UNLESS THE PATIENT QUALIFIES FOR NPEP THROUGH THE PROGRAM
 FOR PREVENTING HIV INFECTION FOR RAPE VICTIMS ESTABLISHED UNDER §
 11–1008 OF THE CRIMINAL PROCEDURE ARTICLE;

25 (2) ADMINISTER THE PROGRAM AND ESTABLISH A STANDARDIZED 26 SET OF GUIDELINES FOR PRIVATE AND PUBLIC ENTITIES <u>PHARMACISTS</u> 27 PARTICIPATING IN THE PROGRAM TO USE IN DEVELOPING AND CONDUCTING 28 PATIENT EDUCATION AND TRAINING ON NPEP THAT INCLUDES:

- 29
- (I) **AVOIDING EXPOSURE TO HIV;**

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$\frac{1}{2}$	(II) RESPONDING TO EXPOSURE TO HIV WITH THE APPROPRIATE USE OF NPEP;
$\frac{3}{4}$	(III) ACCESS TO NPEP AND THE APPROPRIATE FOLLOW-UP AFTER THE ADMINISTRATION OF NPEP; AND
5	(IV) ENGAGEMENT IN ADDITIONAL CARE INCLUDING:
$6\\7$	1. Access to pre-exposure prophylaxis (PrEP); and
8 9	2. HARM REDUCTION PROGRAMS FOR PATIENTS WITH CONTINUING RISK OF EXPOSURES; AND
10 11	(3) COLLECT AND REPORT DATA ON THE OPERATION AND RESULTS OF THE PROGRAM.
12	13-5203.
13 14	(A) AT THE TIME OF DISPENSING NPEP, A PHARMACIST REGISTERED WITH THE PROGRAM SHALL:
$\begin{array}{c} 15\\ 16 \end{array}$	(1) SCREEN THE PATIENT TO DETERMINE THAT HIV EXPOSURE OCCURRED WITHIN 72 HOURS BEFORE THE DISPENSING;
17 18	(2) DETERMINE WHETHER THE PATIENT MEETS CLINICAL CRITERIA CONSISTENT WITH <u>THE MOST RECENT</u> CDC GUIDELINES, INCLUDING THE :
19 20	(I) <u>The</u> identification of any contraindicated medications; <u>and</u>
$\begin{array}{c} 21 \\ 22 \end{array}$	(II) IF APPLICABLE, EXPOSURE AS THE RESULT OF AN ALLEGED RAPE OR SEXUAL OFFENSE OR ALLEGED CHILD SEXUAL ABUSE;
$\begin{array}{c} 23\\ 24\\ 25 \end{array}$	(3) SUBJECT TO SUBSECTION (B) OF THIS SECTION, DETERMINE WHETHER AN AVAILABLE STANDING ORDER IS APPROPRIATE FOR THE PATIENT AND DISPENSE NPEP IN ACCORDANCE WITH <u>THE MOST RECENT</u> CDC GUIDELINES;
$\frac{26}{27}$	(4) REFER THE PATIENT TO A DISEASE INTERVENTION SPECIALIST WITHIN THE DEPARTMENT FOR ONGOING TREATMENT; AND
28 29	(5) DETERMINE WHETHER THE PATIENT HAS A PRIMARY CARE PROVIDER AND:

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1(I)IF THE PATIENT HAS A PRIMARY CARE PROVIDER, NOTIFY2THE PROVIDER THAT THE PATIENT WAS DISPENSED NPEP; OR

3 (II) IF THE PATIENT DOES NOT HAVE A PRIMARY CARE 4 PROVIDER, PROVIDE THE PATIENT WITH A LIST OF <u>LOCAL</u> PRIMARY CARE 5 PROVIDERS AND CLINICS <u>PROVIDED BY THE DEPARTMENT</u>.

6 (B) IF AN AVAILABLE STANDING ORDER IS NOT APPROPRIATE FOR THE 7 PATIENT, THE PHARMACIST SHALL REFER THE PATIENT TO A PRIMARY CARE 8 PROVIDER.

9 (C) A PHARMACIST MAY DISPENSE NPEP IN ACCORDANCE WITH A THERAPY 10 MANAGEMENT CONTRACT UNDER TITLE 12, SUBTITLE 6A OF THE HEALTH 11 OCCUPATIONS ARTICLE.

12 13-5204.

(A) A LICENSED HEALTH CARE PROVIDER WITH PRESCRIBING AUTHORITY
 WHO IS REGISTERED WITH THE PROGRAM MAY DELEGATE THE DISPENSING OF
 NPEP UNDER A STANDING ORDER TO AN EMPLOYEE OR A VOLUNTEER OF AN
 AUTHORIZED PRIVATE OR PUBLIC ENTITY IN ACCORDANCE WITH A WRITTEN
 AGREEMENT UNDER § 13–5205 OF THIS SUBTITLE.

18(B)Any licensed health care provider who has dispensing19Authority may dispense nPEP to an individual in accordance with a20Standing order in accordance with this subsection.

21 **13-5205.**

AN AUTHORIZED PRIVATE OR PUBLIC ENTITY SHALL ENTER INTO A WRITTEN
 AGREEMENT WITH A LICENSED HEALTH CARE PROVIDER WITH PRESCRIBING
 AUTHORITY TO ESTABLISH PROTOCOLS FOR THE PRESCRIBING AND DISPENSING OF
 NPEP TO ANY INDIVIDUAL IN ACCORDANCE WITH THIS SUBTITLE.

Article – Health Occupations

27 12–101.

26

- 28 (a) In this title the following words have the meanings indicated.
- 29 (x) (1) "Practice pharmacy" means to engage in any of the following activities:
- 30 (i) Providing pharmaceutical care;

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$\frac{1}{2}$	devices;	(ii)	Compounding, dispensing, or distributing prescription drugs or			
3		(iii)	Compounding or dispensing nonprescription drugs or devices;			
4 5	drugs or devices;	(iv)	Monitoring prescriptions for prescription and nonprescription			
6 7 8	patients and healt nonprescription dr		Providing information, explanation, or recommendations to practitioners about the safe and effective use of prescription or devices;			
9 10	monitoring of there	(vi) apy wit	Identifying and appraising problems concerning the use or th drugs or devices;			
$\begin{array}{c} 11 \\ 12 \end{array}$	as provided under	(vii) Subtitl	Acting within the parameters of a therapy management contract, e 6A of this title;			
$13 \\ 14 \\ 15$	title or self–admini § 12–509 of this tit	istered	Administering vaccinations in accordance with § 12–508 of this drugs or maintenance injectable medications in accordance with			
$16 \\ 17 \\ 18$	pharmacy student, training program;	(ix) , or an	Delegating a pharmacy act to a registered pharmacy technician, individual engaged in a Board approved pharmacy technician			
19 20 21	pharmacy technici pharmacy technici		Supervising a delegated pharmacy act performed by a registered armacy student, or an individual engaged in a Board approved ning program;			
$\begin{array}{c} 22\\ 23 \end{array}$	19–713.6 of the He		Providing drug therapy management in accordance with § General Article;			
24 25 26	self–administered Administration; [o:	contr	Prescribing and dispensing contraceptive medications and aceptive devices approved by the U.S. Food and Drug			
27 28	medications; OR	(xiii)	Prescribing and dispensing nicotine replacement therapy			
29 30 31 32 33 34	PROGRAM ESTAB PRESCRIBING AN (NPEP) MEDICAT	LISHE D DISF FION A	IF THE PHARMACIST IS REGISTERED WITH THE OSTEXPOSURE PROPHYLAXIS (NPEP) STANDING ORDER D UNDER § 13–5202 OF THE HEALTH – GENERAL ARTICLE, PENSING NONOCCUPATIONAL POSTEXPOSURE PROPHYLAXIS PPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION WITH "UPDATED GUIDELINES FOR ANTIRETROVIRAL			

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1 POSTEXPOSURE PROPHYLAXIS AFTER SEXUAL, INJECTION DRUG USE, OR OTHER

2 NONOCCUPATIONAL EXPOSURE TO HIV – UNITED STATES 2016" OR SUBSEQUENT 3 GUIDELINES PUBLISHED BY THE FEDERAL CENTERS FOR DISEASE CONTROL AND

4 **PREVENTION**.

5 (2) "Practice pharmacy" does not include the operations of a person who 6 holds a permit issued under § 12–6C–03 of this title.

7 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 8 October 1, 2024.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.