SB0246 2024 Annapolis Pride.pdf

Uploaded by: Jaden Farris
Position: FAV

Board of Directors

Chair
Joe Toolan
(he/him)

Vice-Chair
Katie Connolly
(they/them)

Treasurer
Dennis McGowan
(he/him)

Secretary
Jaden Farris
(he/him)

Valerie Anias
(she/her)

Christine Feldmann
(she/her)

Mastin Fowler
(he/him)

Chris Haley
(he/him)

David Jones
(he/him)

Nicole McCoy
(she/her)

Jessica Parsell
(she/her)

Sarah Sample
(she/her)

Joshua Seefried
(he/him)

Jayne Walters
(she/her)

Tim Williams
(he/him)

BILL: Senate Bill 246 - Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment
DATE: January 30, 2024
POSITION: FAVORABLE
COMMITTEE: Finance
CONTACT: Jaden Farris ┃ jaden@annapolispride.org

Annapolis Pride's mission is to advocate for, empower, and celebrate the LGBTQ+ community in Anne Arundel County to live fully and authentically. Our vision is a safe, equitable, and anti-racist community where people of all identities thrive.

As such, Annapolis Pride supports Senate Bill 246, which is a crucial step towards strengthening public health efforts in Maryland. While PEP significantly decreases the risk of contracting HIV if administered within 72 hours, with the greatest efficacy within the first few hours, access barriers and long emergency room wait times hinder timely administration. [1]

Additionally, the nPEP Standing Order Program authorizing pharmacists and healthcare providers to dispense PEP without requiring a prescription. This legislation makes this lifesaving medication available in more convenient locations, such as pharmacies and community health centers. This will significantly reduce wait times and make PEP accessible to individuals who might otherwise struggle to reach a medical provider withing the crucial 72-hour window.

Accordingly, Annapolis Pride respectfully requests a **favorable** committee report on Senate Bill 246.

---

[1] DeHaan E, McGowan JP, Fine SM, et al. PEP to Prevent HIV Infection [Internet]. Baltimore (MD): Johns Hopkins University; 2022 Aug 11. Available from: https://www.ncbi.nlm.nih.gov/books/NBK562734/

SB0246 2024 Annapolis Pride.pdf
Uploaded by: Jaden Farris
Position: FAV

Board of Directors

Chair
Joe Toolan
(he/him)

Vice-Chair
Katie Connolly
(they/them)

Treasurer
Dennis McGowan
(he/him)

Secretary
Jaden Farris
(he/him)

Valerie Anias
(she/her)

Christine Feldmann
(she/her)

Mastin Fowler
(he/him)

Chris Haley
(he/him)

David Jones
(he/him)

Nicole McCoy
(she/her)

Jessica Parsell
(she/her)

Sarah Sample
(she/her)

Joshua Seefried
(he/him)

Jayne Walters
(she/her)

Tim Williams
(he/him)

BILL: Senate Bill 246 - Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment
DATE: January 30, 2024
POSITION: FAVORABLE
COMMITTEE: Finance
CONTACT: Jaden Farris | jaden@annapolispride.org

Annapolis Pride's mission is to advocate for, empower, and celebrate the LGBTQ+ community in Anne Arundel County to live fully and authentically. Our vision is a safe, equitable, and anti-racist community where people of all identities thrive.

As such, Annapolis Pride supports Senate Bill 246, which is a crucial step towards strengthening public health efforts in Maryland. While PEP significantly decreases the risk of contracting HIV if administered within 72 hours, with the greatest efficacy within the first few hours, access barriers and long emergency room wait times hinder timely administration. [1]

Additionally, the nPEP Standing Order Program authorizing pharmacists and healthcare providers to dispense PEP without requiring a prescription. This legislation makes this lifesaving medication available in more convenient locations, such as pharmacies and community health centers. This will significantly reduce wait times and make PEP accessible to individuals who might otherwise struggle to reach a medical provider withing the crucial 72-hour window.

Accordingly, Annapolis Pride respectfully requests a **favorable** committee report on Senate Bill 246.

---

[1] DeHaan E, McGowan JP, Fine SM, et al. PEP to Prevent HIV Infection [Internet]. Baltimore (MD): Johns Hopkins University; 2022 Aug 11. Available from: https://www.ncbi.nlm.nih.gov/books/NBK562734/

1a - SB 246 -FIN - MDH -LOS (1).pdf

Uploaded by: Jason Caplan

Position: FAV

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

January 30, 2024

The Honorable Pamela Beidle
Chair, Finance Committee
3 East Miller Senate Office Building
Annapolis, MD 21401-1991

RE: SB 246 – Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment – Letter of Support

Dear Chair Beidle:

The Maryland Department of Health respectfully submits this letter of support for SB 246 – Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment. The nPEP Standing Order Program provides for dispensing of nPEP by Maryland pharmacists to individuals at risk of contracting human immunodeficiency virus (HIV) following isolated sexual, injection drug use, or other nonoccupational HIV exposure. As of September 2023, pharmacists in 17 states have some degree of authority to provide nPEP to their patients[1].

nPEP is a 28-day course of three antiretroviral medications that can be taken after a sexual encounter or the sharing of injection equipment that results in a potential exposure to HIV. The primary barriers of nPEP uptake have been awareness by providers and patients and timely access. Studies indicate that when taken within 72 hours of exposure, nPEP is associated with an 80% decrease in the risk of transmission of HIV.[2] However, the efficacy of nPEP decreases by the hour and is ineffective 72 hours post exposure. Since 2005, the Centers for Disease Control and Prevention (CDC) has issued guidance for the provision of nPEP and the medications have been proven cost-effective and well tolerated.

Under SB 246, Maryland residents and visitors will be able to access nPEP directly from a pharmacist. This expanded access would increase utilization of nPEP and significantly decrease

---

[1] *Pharmacists Expand Access to PrEP in 17 States*. Sonjia Collins. Available from the American Pharmacist Association website.

[2] Cardo DM, Culver DH, Ciesielski CA, et al. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. N Engl J Med. 1997; 337: 1485-1490. Available online at: https://www.nejm.org/doi/full/10.1056/NEJM199711203372101; Smith DK, Grohskopf LA, Black RJ, et al.: Antiretroviral postexposure prophylaxis after sexual, injection-drug use, or other nonoccupational exposure to HIV in the United States: recommendations from the U.S. Department of Health and Human Services. MMWR Recomm. Rep. 2005;54(RR-2):1–20. Available online at: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5402a1.htm

potential new HIV infections, as prompt use is integral to nPEP efficacy.

Further, the nPEP Program will position Maryland as a leader in achieving the goals outlined in the US Department of Health and Human Services "Ending the HIV Epidemic in the United States." This federal initiative addresses the ongoing HIV public health crisis by leveraging data and tools available to reduce new HIV infections in the US by 90 percent by 2030.[3]

The Department notes that increasing access to nPEP in Maryland would amplify the effectiveness of our primary prevention strategies, which include condom use and drug-user health programs. MDH would continue to encourage the use of pre-exposure prophylaxis (PrEP), but would increase awareness of nPEP as a secondary emergency measure should a primary prophylactic measure fail.

Leveraging the expertise of pharmacists to dispense nPEP promptly bridges a vital gap in the emergency response to potential HIV exposures among Marylanders made most vulnerable by their lack of access to care. This bill does not diminish the role of physicians; instead, it enhances the overall healthcare system's responsiveness and effectiveness in dealing with HIV emergencies. The collaborative nature of the nPEP Standing Order Program, designed within the bounds of the Department's established authority and with rigorous safeguards and protocols, ensures that pharmacists work in tandem with the Department, healthcare providers, and communities to deliver not just immediate care, but also a pathway to ongoing, comprehensive treatment and support.

The nPEP Standing Order Program would be another tool to reduce new HIV infections, address health disparities, and move Maryland closer to the goal of ending the HIV epidemic in our state.

If you would like to discuss this further, please do not hesitate to contact Sarah Case-Herron, Director of Governmental Affairs at sarah.case-herron@maryland.gov.

Sincerely,

Laura Herrera Scott, M.D., M.P.H.
Secretary

---

[3] Ending the HIV Epidemic in the United States.US Department of Health and Human Services. Available online at: https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/overview/

1b - SB 246 - FIN - MACHO - LOS .pdf
Uploaded by: Maryland State of
Position: FAV

2024 SESSION
POSITION PAPER

BILL:	**SB 246 – Public Health – Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program – Establishment**
COMMITTEE:	**Senate – Finance Committee**
POSITION:	**Letter of Support**
BILL ANALYSIS:	**SB 246 establishes the Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program. The program allows authorized pharmacists to dispense nPEP, a medication to reduce the risk of contracting HIV after potential exposure, following CDC guidelines and in accordance with a standing order. The Maryland Department of Health (MDH) is tasked with adopting regulations and establishing guidelines for participant entities. Pharmacists registered with the program must screen patients, determine eligibility based on CDC Guidelines, provide nPEP when appropriate, and notify or refer to primary care services.**

POSITION RATIONALE: The Maryland Association of County Health Officers (MACHO) strongly supports SB 246. Improving access to nPEP, a drug known to effectively prevent HIV infection following exposure, will decrease the HIV burden in Maryland and disparities in new HIV infections. MACHO supports Maryland joining twelve other states (Arkansas, California, Colorado, Illinois, Maine, Nevada, New Mexico, New York, North Carolina, Oregon, Utah, and Virginia) in authorizing pharmacists to dispense nPEP to eligible residents.[1]

HIV nPEP is highly effective in preventing HIV infection if it is administered within 72 hours of potential exposure. In fact, nPEP is more effective the sooner it is administered following exposure.[2] Accessing nPEP through the traditional medical system can be challenging due to limited hours, difficulty getting appointments, and challenges with transportation. Community pharmacies are highly accessible; 90% of the U.S. population lives within 5 minutes of a pharmacy.[3] Many pharmacies have extended hours beyond those of the traditional medical system, making them well-positioned to administer nPEP, a highly time-sensitive treatment. Local health departments are also uniquely positioned in their communities to be trusted places for this important medical care.

Access to nPEP is also an equity issue. In Maryland, over 30,000 people are living with HIV, and there were 751 new HIV diagnoses in 2022.[4] Over 90% of new HIV cases in Maryland in 2022 occurred among racial/ethnic minorities.[5] Minority populations experience significant barriers to accessing the traditional

[1] National Alliance of State and Territorial AIDS Directors, *Pharmacist Authority to Initiate PrEP & PEP and Participate in Collaborative Practice Agreements*. August 10, 2023. https://nastad.org/resources/pharmacist-authority-initiate-prep-pep-and-participate-collaborative-practice-agreements
[2] US Department of Health & Human Services, *Post-Exposure Prophylaxis.* Updated November 15, 2023. https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/post-exposure-prophylaxis/
[3] Berenbrok et. al. *Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis.* Journal of the American Pharmacists Association. *https://doi.org/10.1016/j.japh.2022.07.003*
[4] Maryland Department of Health, Center for HIV Surveillance, Epidemiology and Evaluation, *Quick Maryland HIV Statistics*. https://health.maryland.gov/phpa/OIDEOR/CHSE/pages/statistics.aspx
[5] Maryland Department of Health, Center for HIV Surveillance, Epidemiology and Evaluation, *HIV In Maryland*, 2022. Updated September 2023. https://health.maryland.gov/phpa/OIDEOR/CHSE/pages/statistics.aspx

healthcare system in comparison to non-Hispanic white residents.[6] Allowing pharmacists to dispense nPEP will help reduce barriers to accessing timely treatment, ultimately, improving health equity.

MACHO supports MDH's efforts to ensure pharmacists provide nPEP while remaining connected to the traditional doctor-patient relationship. SB 246 includes requirements for pharmacists to notify the patient's primary care provider after dispensing nPEP. If the patient does not have a primary care provider, the pharmacist must provide a list of primary care providers and clinics for follow up within the traditional medical system. This will help assure quality and continuance of care for the patient.

For these reasons, MACHO submits this LOS for the Committee's consideration on SB 246. For more information, please contact Ruth Maiorana, Executive Director, MACHO, at rmaiora1@jhu.edu or 410-937-1433. *This communication reflects the position of MACHO.*

---

[6] The Commonwealth Fund, *Achieving Rachial and Ethnic Equity in U.S. Health Care.* November 18, 2021. https://www.commonwealthfund.org/publications/scorecard/2021/nov/achieving-racial-ethnic-equity-us-health-care-state-performance

SB246 - Public Health - Nonoccupational Postexposu

Uploaded by: Matthew Levy
Position: FAV

THE PRINCE GEORGE'S COUNTY GOVERNMENT

OFFICE OF THE COUNTY EXECUTIVE

BILL:	**Senate Bill 246 – Public Health – Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program – Establishment**
SPONSOR:	**Chair, Finance Committee (By Request – Departmental – Health)**
HEARING DATE:	**January 30, 2024**
COMMITTEE:	**Finance**
CONTACT:	**Intergovernmental Affairs Office, 301-780-8411**
POSITION:	**SUPPORT**

The Office of the Prince George's County Executive **SUPPORTS Senate Bill 246**, which establishes establishes the Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program. The program allows authorized pharmacists to dispense nPEP, a medication to reduce the risk of contracting HIV after potential exposure, following CDC guidelines and in accordance with a standing order.

Improving access to nPEP, a drug known to effectively prevent HIV infection following exposure, will decrease the HIV burden in Maryland and reduce disparities in new infections. Prince George's County supports Maryland joining twelve other states (Arkansas, California, Colorado, Illinois, Maine, Nevada, New Mexico, New York, North Carolina, Oregon, Utah, and Virginia) in authorizing pharmacists to dispense nPEP to eligible residents.[1]

HIV nPEP is highly effective in preventing HIV infection if it is administered within 72 hours of potential exposure. In fact, nPEP is more effective the sooner it is administered following exposure.[2] Accessing nPEP through the traditional medical system can be challenging due to limited hours, difficulty getting appointments, and challenges with transportation. In contrast, community pharmacies are highly accessible; 90% of the U.S. population lives within 5 minutes

---

[1] National Alliance of State and Territorial AIDS Directors, *Pharmacist Authority to Initiate PrEP & PEP and Participate in Collaborative Practice Agreements*. August 10, 2023. https://nastad.org/resources/pharmacist-authority-initiate-prep-pep-and-participate-collaborative-practice-agreements

[2] US Department of Health & Human Services, *Post-Exposure Prophylaxis.* Updated November 15, 2023. https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/post-exposure-prophylaxis/

of a pharmacy.[3] Many pharmacies have extended hours beyond those of the traditional medical system, making them well-positioned to administer nPEP, a highly time-sensitive treatment.

Access to nPEP is also an equity issue. In Prince George's County, over 8,000 people are living with HIV, and there were 258 new HIV diagnoses in 2022.[4] Over 90% of new HIV cases in Maryland in 2022 occurred among racial/ethnic minorities.[5] Minority populations experience significant barriers to accessing the traditional healthcare system in comparison to non-Hispanic white residents.[6] Allowing pharmacists to dispense nPEP will help reduce barriers to accessing timely treatment, ultimately, improving health equity.

Prince George's County commends MDH's efforts to ensure pharmacists provide nPEP while remaining connected to the traditional doctor-patient relationship. Senate Bill 246 includes requirements for pharmacists to notify the patient's primary care provider after dispensing nPEP. If the patient does not have a primary care provider, the pharmacist must provide a list of primary care providers and clinics for follow-up within the traditional medical system. This will help ensure quality and continuity of care for the patient.

For the reasons stated above, the Office of the Prince George's County Executive **SUPPORTS Senate Bill 246** and asks for a **FAVORABLE** report.

---

[3] Berenbrok et. al. *Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis.* Journal of the American Pharmacists Association. *https://doi.org/10.1016/j.japh.2022.07.003*

[4] Maryland Department of Health, Center for HIV Surveillance, Epidemiology and Evaluation, *HIV Priority Populations*. 2022.
https://public.tableau.com/app/profile/maryland.department.of.health.hiv.surveillance/viz/MarylandHIVPriorityPopulations/Dashboard1

[5] Maryland Department of Health, Center for HIV Surveillance, Epidemiology and Evaluation, *HIV In Maryland*, 2022. Updated September 2023. https://health.maryland.gov/phpa/OIDEOR/CHSE/pages/statistics.aspx

[6] The Commonwealth Fund, *Achieving Rachial and Ethnic Equity in U.S. Health Care.* November 18, 2021.
https://www.commonwealthfund.org/publications/scorecard/2021/nov/achieving-racial-ethnic-equity-us-health-care-state-performance

2024 ACNM SB 246 Senate Side.pdf

Uploaded by: Robyn Elliott

Position: FAV

Committee:	**Senate Finance Committee**
Bill Number:	**SB 246**
Title:	**Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment**
Hearing Date:	**January 30, 2024**
Position:	**Support**

The Maryland Affiliate of the American College of Nurse Midwives (ACNM) supports *Senate Bill 246 – Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment.* This bill establishes the nPEP Standing Order Program to authorize pharmacists and health care providers to prescribe or dispense nPEP.

PEP, a form of nPEP, is a short-term treatment that must be started as soon as possible after high-risk non-occupational exposure to HIV. With such a narrow window of time, we must develop innovative ways to ensure people who are high-risk can more easily access PEP. Under our current laws, the individual must see a provider for a prescription, which often requires waiting for an appointment and navigating the health care system. Under this bill, pharmacists and non-clinicians could dispense PEP to an individual directly through a written agreement with a prescriber. As a result, outreach and mobile programs could dispense PEP when identifying someone at risk and then link them to the health care system.

With almost 800 newly diagnosed cases of HIV in Maryland in 2021 (the latest year where information is available), we need new public health approaches to disease prevention.[i] We ask for a favorable report. If we can provide any additional information, please contact Robyn Elliott at relliott@policypartners.net or (443) 926-3443.

---

[i] https://www.cdc.gov/hiv/basics/statistics.html

2024 MCHS SB 246 Senate Side.pdf

Uploaded by: Robyn Elliott

Position: FAV

Maryland Community Health System

Committee:	**Senate Finance Committee**
Bill:	**Senate Bill 246 – Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment**
Hearing Date:	**January 30, 2024**
Position:	**Support**

Maryland Community Health System (MCHS) supports *Senate Bill 246 – Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment*. This bill establishes the nPEP Standing Order Program to authorize pharmacists and health care providers to prescribe or dispense nPEP.

nPEP is a short-term treatment that must be started as soon as possible after high-risk non-occupational exposure to an infectious agent, such as HIV. Maryland Community Health System is a network of federally qualified health centers, we regularly serve those with heightened risk of contracting HIV regardless of ability to pay, making the MCHS network potential sites for nPEP delivery. Standing orders are regularly used by health care providers to streamline workflow and effectively increase patient access to healthcare. Passage of House Bill 127 will provide our staff a much needed resource for patients to gain access to this time-sensitive treatment.

According to the CDC, there were nearly 800 people newly infected with HIV in Maryland in 2021.[i] We ask for a favorable report on this legislation, as it will provide Maryland with another public health tool to lower HIV rages. If we can be helpful in any way, please let us know by contacting Robyn Elliott at relliott@policypartners.net.

---

[i] https://www.cdc.gov/hiv/basics/statistics.html

2024 MNA SB 246 Senate Side.pdf
Uploaded by: Robyn Elliott
Position: FAV

Committee: **Senate Finance Committee**

Bill Number: **Senate Bill 246 – Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment**

Hearing Date: **January 30, 2024**

Position: **Support**

The Maryland Nurses Association (MNA) supports *Senate Bill 246 – Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment*. This bill establishes the nPEP Standing Order Program to authorize pharmacists and non-clinicians to dispense nPEP under written orders with a prescriber.

Maryland continues to experience too-high rate of infections for HIV. In 2021, 749 new people were diagnosed with HIV[i]. Under the bill, the Marland Department of Health (MDH) is proposing a a public health strategy to reach more people with nPEP in time to reduce their risk on contracting HIV. It can take too long for at-risk individuals to obtain nPEP if they have to obtain appointments with providers. The bill will allow pharmacists and community programs to dispense nPEP to individuals who have been exposed to HIV and then link them to the health care system for follow-up care.

We ask for a favorable report. If we can provide any additional information, please contact Robyn Elliott at relliott@policypartners.net or (443) 926-3443.

---

[i] https://www.cdc.gov/hiv/basics/statistics.html

2024 WLCM SB 246 Senate Side.pdf

Uploaded by: Robyn Elliott

Position: FAV

Women's Law Center of Maryland
JUSTICE FAIRNESS EQUALITY
102 West Pennsylvania Avenue, Suite 100 Towson, MD 21204
phone 410-321-8761 fax 410-321-0462 www.wlcmd.org

Committee: **Senate Finance Committee**

Bill number: **Senate Bill 246 - Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment**

Hearing Date: **January 30, 2024**

Position: **Support**

The Women's Law Center of Maryland supports *Senate Bill 246 – Public Health – Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program – Establishment.* If enacted, the legislation would remove barriers for people obtaining PEP, an essential medication that reduces the risk of HIV infection. Increased access to PEP is critical for survivors of sexual assault and domestic violence, as they are at heightened risk for HIV.

Under Maryland's current law, individuals can only obtain PEP through a prescription from a prescriber. When people are marginalized from the health care system, this requirement can be an almost insurmountable barrier to obtaining timely medication. PEP must be taken within 72 hours of HIV exposure to be effective.

The legislation would remove barriers to PEP by allowing pharmacists and non-clinicians in community programs to dispense PEP under a standing order. A standing order is a written agreement between a prescriber and other individual to dispense medication. This arrangement would allow an individual to obtain PEP from a pharmacy or a community-based program, including mobile crisis clinics. The individuals would then also be linked to a health care provider for ongoing services.

We ask for a favorable report. If any further information would be helpful, please contact Robyn Elliott at relliott@policypartners.net.

SB246.nPEP.MPhA-combined.pdf
Uploaded by: Aliyah Horton
Position: FWA

MPhA
MARYLAND PHARMACISTS ASSOCIATION

Date: January 30, 2024
To: The Honorable Pamela Beidle, Chair
From: Aliyah N. Horton, FASAE, CAE, Executive Director, MPhA, 240-688-7808
Cc: Senate, Finance Committee
Re: SUPPORT WITH AMENDMENT – SB246 - Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment

The Maryland Pharmacists Association (MPhA) largely supports the passage of SB 246, which would authorize pharmacists to dispense HIV post-exposure prophylaxis (PEP) medications under a statewide standing order. HIV PEP medication is emergency medication and must be utilized within the required 72-hour window after possible exposure. The process outlined in the bill would improve access to HIV PEP and support greater patient connections to state HIV education, care prevention and support resources.

CURRENT PROCESS	PROPOSED PROCESS
Patient visits urgent care, ER or seeks primary care physician appointment within the first 72 hours of exposure	Patient visits pharmacy within 72 hours of exposure
Physician writes prescription	Pharmacist screens and may dispenses PEP via standing order
Patient visits pharmacist to get prescription filled	Provides counseling and bridge to MDH support
Pharmacist counsels and dispenses PEP	

- According to HIV.gov "while new HIV diagnoses have declined significantly from their peak, progress on further reducing them has stalled with an estimated 40,000 Americans being newly diagnosed each year. Without intervention another 400,000 Americans will be newly diagnosed over 10 years despite the available tools to prevent infections."

- Maryland has been ranked 12th among states and territories in adult/adolescent HIV diagnosis rates (per 100,000) in 2021. The Department of Health shows the highest rates are seen in Prince George's County and Baltimore City, next highest rates are in the rural counties of Western Maryland, Eastern Shore, and Southern Maryland.

- Nationally efforts have identified, 48 counties in the US as having the highest HIV burden in the United States - Montgomery and Prince Georges County and Baltimore City are included in that number.

- Pharmacists are a resource available to Marylanders, as they can assist in preventing the spread of HIV and reduce longer-term healthcare costs by serving as an immediate community intervention point.

- Pharmacies offer stigma-free access to HIV prevention medications and linkage to care services in communities that face the highest risk (rural, low-income, sexual assault victims, intravenous drug users).

- Lifetime medical costs for HIV are estimated to range from the mid-$300,000 to almost $500,000 per person.

- The Standing order allows the State Health Director with an MD or other health care provider with prescriptive authority to issue a non-patient specific standing order for PEP that any pharmacist within the state nPEP program may utilize.

- The bill would authorize pharmacists to screen patients to identify whether the exposure meets the clinical criteria and whether medication can be initiated within the designated timeframe.

- Pharmacists already assist with a variety of issues related to general health and medication adherence – including knowledge of insurance, patient assistance programs and other resources.

- States that have state-wide standing order for at least HIV nPEP include AZ, AR, CA, CO, IL, ME, NV, NM, NY, NC, OR, UT and VA.

- We believe this bill is a strong step forward in addressing HIV prevention needs in Maryland, which has been identified as a national focus area. We do have questions/concerns to clarify education provisions, testing, program administration and administrative requirements. We look forward to discussing our questions during the subcommittee/stakeholder deliberations.

Additional Resources:

- For your reference, please see attached report: *The Role of Community Pharmacies in Providing Access to HIV Post-exposure Prophylaxis* (PEP), which further supports the goals of SB 246.
- 2022 Maryland Pharmacists State Fact Sheet

MARYLAND PHARMACISTS ASSOCIATION

Founded in 1882, MPhA is the only state-wide professional society representing all practicing pharmacists in Maryland. Our mission is to strengthen the profession of pharmacy, advocate for all Maryland pharmacists and promote excellence in pharmacy practice.

Journal of Community Health
https://doi.org/10.1007/s10900-023-01281-x

REVIEW

The Role of Community Pharmacies in Providing Access to HIV Post-exposure Prophylaxis (PEP)

Kaylee Scarnati[1] · Katherine Esser[1] · Eric G. Sahloff[2] · Joan Duggan[1]

Accepted: 25 August 2023
© The Author(s), under exclusive licence to Springer Science+Business Media, LLC, part of Springer Nature 2023

Abstract
HIV affects an estimated 1.2 million individuals in the United States and is disproportionately concentrated among African Americans, Latinos, and people of multiple races. Post-exposure prophylaxis (PEP) substantially decreases HIV transmission when started within 72 h after exposure, but problems of accessibility have hindered its widespread usage in communities at risk for HIV infection. Pharmacy-initiated PEP access was first permitted in New York City in 2017, allowing pharmacists to provide a 7-day supply of PEP without a prescription for consumers at high risk for HIV infection. It was expected that the broad reach and accessibility of community pharmacies would increase timely access to PEP for all individuals, especially those who already face significant barriers to accessing the healthcare system. Since then, eleven other states have followed suit and expanded the scope of outpatient pharmacy practice in order to increase the availability of HIV PEP but prescribing laws in over 75% of the US have not been changed. Much of the existing literature on HIV prevention focuses on PrEP access barriers with limited information on PEP access in the US. In this paper, we review the current status of pharmacist-initiated PEP in the US as part of the End the HIV Epidemic (EHE) initiative.

Keywords Post-exposure prophylaxis · HIV · Pharmacy · Community

Background

The Center for Disease Control (CDC) estimates that 1.2 million individuals in the United States have HIV [1]. Incidence is not stratified equally, disproportionately affecting African Americans, Hispanics, and persons of multiple races. Currently, modeling data from the CDC estimates a lifetime risk of HIV infection among Black men who have sex with men (MSM) as 1 in 2, compared to the 1 in 11 lifetime risk for white MSM. New HIV diagnosis in the US declined by 12% from 2017 to 2021, dropping from approximately 36,500 infections per year to about 32,100 infections per year [2]: the effect of the coronavirus pandemic resulting in decreased routine HIV testing may be a factor for this decreased incidence. However, during that time, decreased rates of new HIV infections were still not spread equally among all ethnic groups. While new HIV infections decreased by 45% in whites, they decreased by only 36% in Hispanic/Latino Americans and 27% in Black/African Americans. These results highlight the continued disparities in the acquisition of HIV infection and the continued need to find effective strategies that allow increased universal access to HIV prevention tools for all ethnic groups, especially those affected by adverse social determinants of health (SDOH) [2].

In 2019, the U.S. Department of Health and Human Services introduced the *Ending the HIV Epidemic in the U.S. (EHE)* initiative, which aims to decrease HIV infections by 90% by 2030; this will result in an estimated 3000 new infections annually compared to the current incidence of > 30,000 new infections per year [3]. The COVID pandemic shifted money and resources away from this initiative, and currently, a substantial rejuvenation of efforts is being undertaken now to reach EHE 2030 targets.

Kaylee Scarnati, Katherine Esser have shared first author status equally.

Eric G. Sahloff
eric.sahloff@utoledo.edu

1 Division of Infectious Disease/Department of Internal Medicine, University of Toledo, College of Medicine and Life Sciences, Toledo, USA

2 Department of Pharmacy Practice, University of Toledo, College of Pharmacy and Pharmaceutical Sciences, Toledo, USA

Published online: 27 September 2023

Several prevention strategies, such as treatment as prevention (TasP), syringe exchange programs (SSP), pre-exposure prophylaxis (PrEP), and post-exposure prophylaxis (PEP) are paramount to the success of EHE. PEP is a combination of antiretroviral medications which must be initiated within 72 h after possible or known exposures to HIV in either the occupational or non-occupational setting. PEP is extremely effective but has a narrow time window for acquisition and initiation which makes accessibility permanent to success, but also difficult to execute after non-occupational exposures. Given the potential complexities with accessing non-occupational PEP (nPEP), we briefly review nPEP, barriers to nPEP access, and the potential role of pharmacist-prescribed nPEP in the community pharmacy setting as part of the EHE strategy.

Post-Exposure Prophylaxis

Time is of the essence when PEP is needed after a potential HIV exposure. To be effective, current guidelines recommend initiation of PEP within 72 h (ideally within 2–24 h) of the suspected HIV exposure, and subsequently continued for 28 days [4]. Efficacy of PEP has been estimated through clinical, observational, and animal studies, although this has been difficult to assess in large-scale prospective clinical trials. Several observational and retrospective studies have suggested that PEP is highly effective [5–7]. In 1998, the introduction of protease inhibitors into the occupational PEP recommendations occurred [5]. The availability of effective antiretroviral (ART) medications decreased the incidence of healthcare worker (HCW) seroconversion after exposure to HIV. By 1999, there were 208 confirmed/possible cases of occupationally acquired HIV, but since 2000, there have been no confirmed cases of seroconversion from exposures in the clinical setting [6]. Regarding non-occupational PEP (nPEP), one pilot project followed 267 patients who received nPEP within 72 h after a high-risk sexual exposure [7]. Seroconversion occurred in 7 patients (2.62%) over a 6-month period. In these patients, nPEP was started after 48 h in 4 out of 7 patients and 6 out of 7 patients had re-exposures. Only 1 out of the 267 (0.3%) patients who started nPEP within 48 h after exposure and were without re-exposures during the study period seroconverted, suggesting significant efficacy of nPEP when started in a timely manner in the community setting. Although limited, the data highlights the need for timely patient evaluation for nPEP and rapid access to antiretroviral medications to minimize the risk of HIV infection.

Post-Exposure Prophylaxis Access

Because PEP is an urgent and time-sensitive intervention, maximizing rapid access to antiretroviral therapy has long been recognized as the highest priority for this intervention. For example, the Occupational Safety and Health Administration (OSHA) requires all employees at risk of HIV infection from occupational exposure be able to access PEP "within hours, and not be delayed" [8]. In 2013, OSHA issued a directive stating that "the U.S. Public Health Service Guidelines recommend that PEP be initiated as soon as possible, preferably within hours of exposure. PEP has been shown to be less effective when the administration is delayed. The CDC regards occupational exposures to HIV as urgent medical concerns that should be evaluated immediately" [9]. Despite the efficacy of PEP in decreasing occupational HIV transmission in the healthcare setting, nPEP has not been utilized to its fullest extent in the non-occupational setting due to multiple barriers including awareness of need from both patients and providers, access to medications, and other barriers such as stigma and poverty. Awareness of nPEP among potential consumers and providers of nPEP varies. Amongst providers in areas with above-average HIV prevalence, 44% had prescribed PEP, 43.5% were aware of PEP but had never prescribed it, and 12.5% were unaware of PEP [10]. In the U.S. South, which notably has the highest rates of HIV in the country, fewer providers had prescribed PEP compared to providers in other regions [10, 11]. In fact, of at-risk persons who visited a health care provider in this area, greater than 75% were not even offered a baseline HIV test which is an integral step in the nPEP process [12].

Patient education about the need for nPEP is also vital. In a study in New York City where direct pharmacy access to nPEP starter packs was made available to patients at high risk for HIV infection, utilization was low [13]. In this pilot project aimed at providing nPEP to people who inject drugs, over 400 study participants were enrolled but only three requested nPEP through the pharmacy access pilot program. The main reason cited by study participants for lack of use of this program was their perception of the lack of risk of HIV acquisition, despite high-risk activities.

Timely access to PEP is imperative to minimize the potential for HIV transmission as prevention of HIV infection after exposure is considered a medical emergency. Emergency rooms, urgent care centers, primary care physicians, and specialty clinics such as Infectious Diseases clinics are potential providers of PEP. While many may argue that emergency rooms and urgent cares are already able to cover instances in which an individual cannot get in to see their provider for an urgent evaluation, challenges to

accessing nPEP via emergency rooms or urgent care centers exist and include travel times, wait times, high costs, potential denials by insurance companies, availability of medications, and fear of stigma related to seeking HIV-related care. Patients who do not have established relationships with a primary care physician or ID specialist are often not able to schedule an urgent appointment.

To make nPEP universally available, it is imperative that other providers are available to fill in these gaps in care. To address some of these barriers, one strategy that has been gaining momentum for improving timely access to PEP is the use of community pharmacies. In recent years, twelve states have passed legislation supporting the furnishing of PrEP and/or PEP by pharmacists (see Fig. 1). The authority for pharmacist prescribing or furnishing of nPEP is defined primarily through government-defined protocols or standing orders. Some states allow the delivery of pharmaceutical agents that could include PrEP or nPEP through prescriptive authority or collaborative practice agreements or CPAs (including Ohio, Wisconsin, Tennessee, Florida, Iowa, Washington, Massachusetts, Montana, Idaho, Nebraska, Michigan, and Pennsylvania). Multiple states have legislation that could impact pharmacists' ability to provide PrEP, PEP, or HIV treatments either pending or previously proposed as of this writing (including Massachusetts, Ohio, New Jersey, Minnesota, Florida, and Maryland). However, only the states listed in Table 1 codify and legally protect the ability of pharmacists to provide nPEP. To date, there have been no legal challenges to pharmacist prescriptive authority for nPEP in states such as Idaho.

Community pharmacy is a broad term that includes retail pharmacies (chains, grocery stores), health system pharmacies (outpatient, clinics, specialty offices), and non-traditional options such as workplace pharmacies and church pharmacies [14]. There are many benefits to using community pharmacies as a source of rapid access to PEP. Use of a pharmacy does not require an appointment, most have extended hours and weekend availability, and are ubiquitously located. While most Americans cannot easily access a medical provider for medication that must be administered urgently, most Americans are located within driving distance of a pharmacy. Geographically, nine in ten Americans live within 5 miles of a pharmacy [15]. Comparatively, only 58% of American live within 5 miles of a hospital [16]. This means that, especially in rural areas, traveling to a pharmacy may be easier than emergently accessing a health care provider. As cost is a major obstacle to the acquisition of nPEP, a pharmacist's knowledge about insurance, patient assistance programs, or other potential resources is invaluable. An additional consideration with PEP is the stigma associated with seeking care related to HIV in many medical settings. A community pharmacy may be considered a trusted and neutral setting and may be more acceptable in this regard. Many of those who are at the highest risk for HIV infection are also those most likely to suffer from adverse SDOH including lack of insurance, lack of available providers, and other

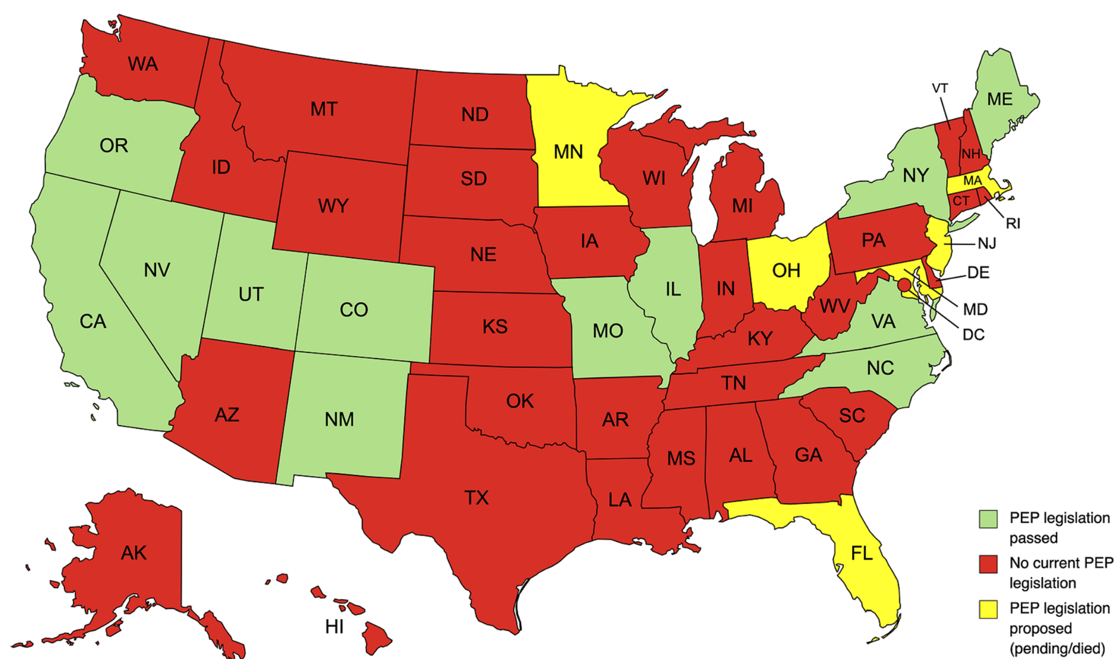


Fig. 1 Legislative outcomes regarding HIV post-exposure prophylaxis (PEP) prescribing by community pharmacists per state

Table 1 States with HIV post-exposure (PEP) legislation as of July 31, 2023

State	HIV prevention-specific legislation[a]	Standing Order/Prescriptive authority/BOP Protocol	Duration of PEP	Provider notification required	PEP-specific Training program	Insurance coverage addressed	Reimbursement for services	Liability
California	SB 159 [21]	Statewide protocol	Full course	Yes	Yes	Yes	Yes	NS
Colorado	HB 1061 [22]	Collaborative Pharmacy Practice Statewide protocol or standing order [23]	Full course	Yes	Yes	Yes	Yes	Yes
Illinois	HB 4430 [24]	Standing order with state licensed physician or medical director of county/local health department	NS	Yes	Yes	Yes	Yes	NS
Maine	LD 1115 [25]	Standing order, CPA, or Board approved protocol	Full course	Yes	Yes	Yes	NS	NS
Missouri	HB 476 [26] 20 CSR 2220–6.025 [27]	Protocol authorized by licensed physician, medical staff committee or standing order issued by Missouri Dept. of Health and Senior Services	Full course	Yes	Yes	NS	NS	NS
New Mexico	NMAC 16.19.26 (BOP) Rx prescriptive authority [28]	Prescriptive authority; prescribe drugs in conjunction w/ POCT BOP statewide protocol [29]	Full course	Yes	Yes	NS	NS	NS
New York	SB129 [30]	Licensed medical provider CPA for non-patient specific standing order	Dispense 7 days of PEP without prescription	Yes	NS	NS	NS	NS
Nevada	SB 325 [31] BOP: LCB File No. R039-21 [32]	BOP established statewide protocol	Full Course	NS	Yes (per board)	Yes	Yes	Yes
North Carolina	HB 96 [33]	Statewide protocol/standing order from State Dept of Health and Human Services [34]	Full course	Yes	[b]	NS	NS	NS
Oregon	HB 2958 [35] OAR 855–020-0110 (prescriptive authority) [36]	Rx prescriptive authority; Statewide protocol developed by BOP [37]	Full course	Yes	NS	Discussed	Discussed	NS
Utah	HB 178 [38]	Rx Prescriptive authority; Division of Occupational and Professional Licensing statewide protocol [39]	Full course	Yes	NS	NS	NS	NS
Virginia	HB2079 [40]	Statewide protocol with collaboration from BOP, BOM, DOH [41]	Full course	Yes	Yes	NS	NS	Yes

BOP Board of Pharmacy, *BOM* Board of Medicine, *CPA* Collaborative practice agreement, *DOH* Department of Health, *NS* not specified

[a]Legislation covers both PrEP and PEP for all states excluding New York and New Mexico

[b]"Immunizing pharmacist"—BLS training, vaccine certified, CE requirements; no HIV-specific training required. Full course = 28–30 day supply of appropriate PEP medication regimens

systemic issues which often compromise their health. Thus, the populations that are currently facing the most barriers to access may be more likely to engage with their community pharmacist than other providers. As such, community pharmacy-led PEP may fill this gap in care with an at-risk patient population and serve as an integral part of the US EHE plan.

The inclusion of pharmacists practicing in the community setting is being increasingly recognized as an opportunity to increase patient access to nPEP. Organizations, such as the National Alliance of State & Territorial AIDS Directors (NASTAD) have outlined the benefits of pharmacist-initiated PrEP and nPEP and literature on model pharmacies has been published [17–20]. As noted previously, multiple states have begun to trial pharmacy-led PrEP and nPEP programs, passing novel legislation to expand pharmacist scope to include the prescription of nPEP or utilizing existing legislation (ex. states with prescriptive authority) to allow pharmacists to prescribe or furnish nPEP. Most states provide a statewide standing order or protocol developed by the Board of Pharmacy or Medicine or the state health department which details requirements for pharmacist-prescribing of nPEP. A few states, like Illinois and New York, require pharmacists to enter into a non-patient specific collaborative practice agreement with state-licensed medical providers. Other specific guidance or requirements of the legislation varies among the states in multiple content areas including duration of or supply limits for antiviral medications, pharmacist education requirements, notification of primary care provider/or provision of information for primary care to those who do not have a primary care provider, criteria for referral to medical providers, reimbursement, laboratory analysis, and liability (Table 1) [21–41]. While literature is available describing initial experiences and success with pharmacy-driven PrEP using CPAs, little data exists on the implementation and efficacy of pharmacy-driven PEP based on state legislation or CPAs [18–20]. This may be attributed to the fact that most legislation was only passed in the last few years concurrent with the unexpected disruption of the COVID pandemic. The few available studies do suggest several potential barriers that need to be addressed. In California, for example, a small study was conducted to assess the implementation of SB 159 in the San Francisco Bay Area after the bill was passed in October 2019 [42]. This bill authorized all pharmacists in California to furnish PrEP and PEP with or without a collaborative practice agreement (CPA) after completing a California Board of Pharmacy-approved training program. 'Furnish' is used by the California legislature to mean "supply by any means, by sale, or otherwise" and is in specific contrast to the more restrictive term 'prescribing'. This study showed that only 2.9% of pharmacies in the study area in the San Francisco Bay were furnishing PrEP and PEP under SB 159: less than 1% were furnishing PrEP and PEP under a CPA. In interviews conducted with the pharmacies in the area, commonly cited barriers included a lack of awareness of the bill, a perceived lack of need to 'furnish' PEP and PrEP, lack of access to laboratory testing, lack of staff, COVID-19, and lack of patient awareness [42]. As has often been the case with pharmacy-driven PrEP, community pharmacies engaged in the care of people living with HIV or those at high-risk have been more likely to offer nPEP as well.

Conclusion

To reach the EHE goal of reducing new HIV cases to 90% by 2030, the current PEP access barriers faced by patients at risk for HIV need to be overcome. Racial disparities, lack of provider education and awareness, high cost of medications, limited access to health insurance, and limited access to health care providers and sexual health services are all barriers to the provision of nPEP to potential candidates for nPEP [7]. The community pharmacy-based approach to nPEP prescribing may improve timely access to those in need. Several states have passed legislation allowing for the prescription of nPEP by pharmacists but the extremely limited amount of data available on pharmacy-initiated nPEP makes it difficult to draw conclusions about the actual uptake and success of these programs. Additional information from states able to provide nPEP via legislation or CPA will be vital and will undoubtedly influence the implementation of similar pharmacy-driven PEP programs across the US. Ultimately, the availability of PEP medications in community pharmacies through a pharmacist-driven initiative may be a necessary and appreciated step in ending the HIV epidemic but is still only part of the solution. Individuals need to recognize they are at risk, be aware of potential sites for PEP acquisition, and ultimately seek the necessary care to prevent potential HIV transmission.

Author Contributions All authors contributed to the conception and design of the article. Material preparation, data collection, and analysis were performed by all four authors. The first draft of the manuscript was written by KS and KE, and all authors commented on revisions of the manuscript. All authors read and approved the final manuscript.

Funding All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

Declarations

Competing interest The authors have not disclosed any competing interests.

References

1. Centers for Disease Control and Prevention. Volume 28, number 3. Centers for Disease Control and Prevention. May 23, 2023. https://www.cdc.gov/hiv/library/reports/hiv-surveillance/vol-28-no-3/index.html. Accessed 6 June 2023
2. Centers for Disease Control and Prevention. HIV declines among young people and drives overall decrease in new HIV infections. Centers for Disease Control and Prevention. May 23, 2023. https://www.cdc.gov/media/releases/2023/p0523-hiv-declines-among-young-people.html. Accessed 6 June 2023
3. Centers for Disease Control and Prevention. About Ending the HIV Epidemic Initiative, September 2021. https://www.cdc.gov/endhiv/about.html. Accessed 6 June 2023
4. "Post-Exposure Prophylaxis." *HIV.gov*, www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/post-exposure-prophylaxis. Accessed 6 June 2023.
5. MMWR. Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis. May 15, 1998 / 47(RR-7);1–28
6. Joyce MP, Kuhar D, Brooks JT. Notes from the Field: Occupationally Acquired HIV Infection Among Health Care Workers — United States, 1985–2013. MMWR. January 9, 2015 / 63(53);1245–1246
7. Beymer, M. R., Kofron, R. M., Tseng, C. H., Bolan, R. K., Flynn, R. P., Sayles, J. M., Perez, M. J., Jordan, W. C., & Landovitz, R. J. (2018). Results from the post-exposure prophylaxis pilot program (P-QUAD) demonstration project in Los Angeles County. *International Journal of STD and AIDS, 29*(6), 557–562.
8. https://www.osha.gov/laws-regs/standardinterpretations/2020-08-19-1. Accessed 15 June 2023.
9. https://www.osha.gov/laws-regs/standardinterpretations/2013-11-27-0. Accessed 15 June 2023.
10. John, S. A., Quinn, K. G., Pleuhs, B., Walsh, J. L., & Petroll, A. E. (2020). HIV Post-exposure prophylaxis (PEP) awareness and non-occupational PEP (nPEP) prescribing history among U.S. Healthcare Providers. *AIDS Behavior., 24*(11), 3124–3131. https://doi.org/10.1007/s10461-020-02866-6
11. "HIV Diagnoses." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 24 Oct. 2022, www.cdc.gov/hiv/statistics/overview/diagnoses.html. Accessed 6 June 2023.
12. Reif, S., Safley, D., McAllaster, C., Wilson, E., & Whetten, K. (2017). State of HIV in the US deep South. *Journal of Community Health, 42*, 844–853.
13. Lewis, C. F., Lekas, H. M., Rivera, A., et al. (2020). Pharmacy PEP access intervention among persons who use drugs in New York City: IPEPcare study—rethinking biomedical HIV prevention strategies. *AIDS and Behavior, 24*, 2101–2111. https://doi.org/10.1007/s10461-019-02775-3
14. Goode, J. V., Owen, J., Page, A., & Gatewood, S. (2019). Community-based pharmacy practice innovation and the role of the community-based pharmacist practitioner in the United States. *Pharmacy (Basel)., 7*(3), 106. https://doi.org/10.3390/pharmacy7030106
15. Berenbrok, L. A., Tang, S., Gabriel, N., Guo, J., Sharareh, N., Patel, N., et al. (2022). Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis. *Journal of the American Pharmacists Association, 62*, 1816–1822. https://doi.org/10.1016/j.japh.2022.07.003
16. Mitchell, Travis. "Views of Problems Facing Urban, Suburban and Rural Communities." *Pew Research Center's Social & Demographic Trends Project*, Pew Research Center, 30 May 2020, www.pewresearch.org/social-trends/2018/05/22/views-of-problems-facing-urban-suburban-and-rural-communities/
17. National Alliance of State and Territorial AIDS Directors (NASTAD). "Pharmacist- Initiated PrEP and PEP" Information Sheet. NASTAD.org. https://nastad.org/sites/default/files/2021-11/PDF-Pharmacist-Initiated-PrEP-PEP.pdf Accessed 15 June 2023
18. Tung, E. L., Thomas, A., Eichner, A., & Shalit, P. (2018). Implementation of a community pharmacy-based pre-exposure prophylaxis service: A novel model for pre-exposure prophylaxis care. *Sex Health, 15*(6), 556–561.
19. Havens, J. P., Scarsi, K. K., Sayles, H., Klepser, D. G., Swindells, S., & Bares, S. H. (2019). Acceptability and feasibility of a pharmacist-led HIV pre-exposure prophylaxis (PrEP) program in the Midwestern United States. *Open Forum Infectious Diseases*, *6*(10):ofz365. https://doi.org/10.1093/ofid/ofz365.
20. Lopez, M. I., Cocohoba, J., Cohen, S. E., Trainor, N., Levy, M. M., & Dong, B. J. (2019). Implementation of pre-exposure prophylaxis at a community pharmacy through a collaborative practice agreement with San Francisco Department of Health. *Journal of the American Pharmacists Association, 60*, 138–144.
21. California Legislative Information. SB 159. HIV: pre-exposure and post-exposure prophylaxis. https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201920200SB159. Accessed 1 Aug 2023
22. Colorado General Assembly. HBj20–1061. Human Immunodeficiency Virus Infection Prevention Medications. https://leg.colorado.gov/sites/default/files/2020a_1061_signed.pdf. Accessed 1 Aug 2023
23. Code of Colorado Regulations. CCR 719–1 Appendix C. Colorado State Board of Pharmacy Statewide Protocol. Pre-Exposure and Post-Exposure Prophylaxis of HIV. https://drive.google.com/file/d/10vcW8Pq-1rjBjQ3Uvm1ZZPGmHiEOPgWB/view. Accessed 1 Aug 2023
24. Illinois General Assembly. Full Text of HB4430. 102nd general assembly. https://www.ilga.gov/legislation/fulltext.asp?DocName=&SessionId=110&GA=102&DocTypeId=HB&DocNum=4430&GAID=16&LegID=&SpecSess=&Session=. Accessed 1 Aug 2023
25. Maine Legislature. LD 1115. An Act to improve access to HIV prevention medications. https://legislature.maine.gov/bills/getPDF.asp?paper=SP0378&item=1&snum=130. Accessed 1 Aug 2023
26. Missouri General Assembly. HB 476. https://house.mo.gov/billtracking/bills191/hlrbillspdf/1034H.01I.pdf. Accessed 1 Aug 2023
27. Missouri Department of Commerce and Insurance. Division State Board of Pharmacy. 20 CSR 2220–6.025 HIV Post-Exposure Prophylaxis. https://dci.mo.gov/proposed-rule/20CSR2220-6.025.pdf. Accessed 1 Aug 2023
28. New Mexico Administrative Code. NMAC 16.19.26. Occupational and Professional Licensing Pharmacist Prescriptive Authority. https://www.srca.nm.gov/parts/title16/16.019.0026.html. Accessed 1 Aug 2023
29. New Mexico Regulation and Licensing Department. Protocol for pharmacist prescribing HIV post-exposure prophylaxis (PEP) therapy in conjunction with point-of-care testing (POCT). https://www.rld.nm.gov/uploads/files/PEPProtocolALONE.pdf. Accessed 1 Aug 2023
30. New York State Department of Health. The licensed pharmacist's role in initiating HIV post-exposure prophylaxis: overview and frequently asked questions. Published August 2022. https://www.health.ny.gov/diseases/aids/general/pep/docs/pharmacists_role.pdf. Accessed 1 Aug 2023
31. Nevada Electronic Legislative Information System. SB 325. https://www.leg.state.nv.us/App/NELIS/REL/81st2021/Bill/7959/Text. Accessed 1 Aug 2023

32. Nevada State Board of Pharmacy. LCB File No. R039–21. https://www.leg.state.nv.us/Register/2021Register/R039-21AP.pdf. Accessed 1 Aug 2023
33. North Carolina General Assembly. HB 96. https://www.ncleg.gov/Sessions/2021/Bills/House/PDF/H96v5.pdf. Accessed 1 Aug 2023
34. North Carolina Department of Health and Human Services. North Carolina State Health Director's Standing Order for Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus, March 28, 2022. https://www.dph.ncdhhs.gov/docs/PEP-StandingOrder-March2022.pdf. Accessed 1 Aug 2023
35. Oregon State Legislature. HB 2958 (2021). https://legiscan.com/OR/text/HB2958/2021. Accessed 1 Aug 2023
36. Oregon Secretary of State. OAR 855-020-0110: Prescribing Practices. Pharmacist Prescriptive Authority. https://oregon.public.law/rules/oar_855-020-0110. Accessed 1 Aug 2023
37. Oregon Board of Pharmacy. Preventative Care: HIV Post-Exposure Prophylaxis. Statewide drug therapy management protocol for Oregon pharmacists. https://www.oregon.gov/pharmacy/Documents/PrevCare_PEP_Protocol_v.6.2023.pdf. Accessed 1 Aug 2023
38. Utah State Legislature. HB 178. Pharmacy practice modifications. https://le.utah.gov/~2021/bills/hbillenr/HB0178.pdf. Accessed 1 Aug 2023
39. Utah Division of Occupational Professional Licensing. Utah guidance for pre-exposure and post-exposure prophylaxis of HIV. Published September 2021. https://www.dopl.utah.gov/wp-content/uploads/2022/09/utah-guidance-for-pre-exposure-and-post-exposure-prophylaxis-of-hiv.pdf. Accessed 1 Aug 2023
40. Virginia General Assembly. HB 2079. Pharmacists: initiation of treatment with and dispensing and administering drugs and devices. http://leg1.state.va.us/cgi-bin/legp504.exe?212+ful+HB2079ER. Accessed 1 Aug 2023
41. Virginia Department of Health Professionals. Virginia Board of Pharmacy. HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol. https://www.dhp.virginia.gov/pharmacy/docs/protocols/PEPCombinedProtocol12-22-2021.pdf. Accessed 1 Aug 2023
42. Bellman, R., Mohebbi, S., Nobahar, N., Parizher, J., & Apollonio, D. E. (2022). An observational survey assessing the extent of PrEP and PEP furnishing in San Francisco Bay Area pharmacies. *Journal of the American Pharmacists Association (2003), 62*(1), 370-377.e3. https://doi.org/10.1016/j.japh.2021.08.001. Epub 2021 Aug 8.

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Springer Nature or its licensor (e.g. a society or other partner) holds exclusive rights to this article under a publishing agreement with the author(s) or other rightsholder(s); author self-archiving of the accepted manuscript version of this article is solely governed by the terms of such publishing agreement and applicable law.

MARYLAND'S PHARMACISTS

IMPROVING THE HEALTH OF COMMUNITIES

Pharmacists are a valued member of the healthcare team and data shows that there is a need for pharmacist-provided patient care services. The potential impact of implementing programs that provide coverage for these services is great, improving health equity and access to care.

Learn More!

QUALIFIED

Pharmacists are Highly Qualified Healthcare Providers

6+ YEARS

Courses focused on pharmacotherapy, patient education, disease management, and clinical decision-making.

LICENSURE

Pharmacists take the North America Pharmacist Licensure Exam (NAPLEX) & Multistate Pharmacy Jurisprudence Examination (MPJE).

ADDITIONAL EDUCATION

Many pharmacists complete Post-Graduate Residencies, Fellowships, and/or Board Certification in specialty areas.

As of **2004**, all pharmacy school graduates earn the **PharmD** degree...a doctorate degree to reflect the **increased complexity of pharmacotherapy** and **advanced training** required for adequate provision of patient care.

ACCESSIBLE

Pharmacists are the Most Accessible Healthcare Professionals

5,220 Pharmacists in Maryland[1]

89% Americans live within 5 miles of a community pharmacy[2]

Annually, Americans visit their pharmacy **35 times** vs. 4 times at their primary care provider.[3]

Number of pharmacies is **15% higher** than number of provider's offices in communities where more than 30% of households live in poverty.[4]

TEST & TREAT

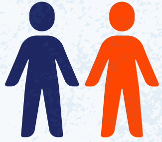
Pharmacists and pharmacies are increasingly offering this public health service of test and treat to promote prevention, early detection, and disease management. Patients are referred when appropriate.

- COVID
- Strep
- Flu
- RSV
- UTI
- STI
- H. pylori
- & others

200% increase

Since May 2020, there has been a 200% increase in the # of pharmacies with CLIA/point of care waivers in the U.S., leading to more pharmacist accessibility for patient care services.[5]

PUBLIC HEALTH IMPACT



Approximately 50% of all adults in the U.S. have one or more chronic disease conditions [6]

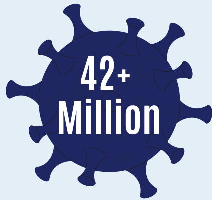
Chronic conditions account for over 85% of total U.S. health care costs [7]

$4

Saved for every $1 spent on pharmacist service. [8]

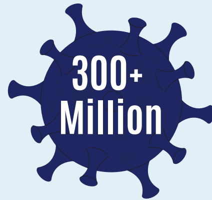
COVID-19

From February 2020 - November 2022, pharmacists in the U.S. provided more than



42+ Million

COVID-19 tests [9]



300+ Million

COVID-19 Vaccinations [9]

Engaging Pharmacists & Their Teams

Expanding the number of pharmacies with **test-and-treat sites** in medically underserved areas could increase access to COVID-19 treatment

39 fold [10]

INFLUENZA

Maryland pharmacists are providing flu shots

TWICE the hours offered for giving immunizations vs. provider's offices [12]

2022 Flu Season

Pharmacies have given **18.7 Million** flu shots

VS

10.7 Million given at provider's offices [11]

6 States now authorize pharmacists to directly prescribe antivirals based on a positive flu test. [13]

Maryland pharmacists should be authorized to do this too!

OPIOID CRISIS

80,000 Americans died from an opioid overdose in 2021. [14]

221 average deaths per day [15]

46 States, **including Maryland,** authorize pharmacists to administer naltrexone to patients. [16]

Naloxone access laws that grant pharmacists direct authority to prescribe are associated with significant reductions in fatal overdoses.

HIV

Pharmacists have been identified by the CDC as key professionals in achieving one of the CDC's goals of ending the HIV Epidemic in the U.S. by preventing HIV infection.

States authorize pharmacists to directly prescribe PrEP. [17]

8

9

States authorize pharmacists to directly prescribe PEP. [17]

This information was developed through a collaboration between NASPA and APhA, with generous support from the Community Pharmacy Foundation.

Access our references at tinyurl.com/2022factsheet
Or scan this QR code

SB 246- (nPEP) Standing Order Program - SWA.pdf
Uploaded by: Jane Krienke
Position: FWA

Maryland
Hospital Association

Senate Bill 246- Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment

Position: ***Support with Amendments***
January 30, 2024
Senate Finance Committee

MHA Position

On behalf of the Maryland Hospital Association's (MHA) 62 member hospitals and health systems, we appreciate the opportunity to comment in support of Senate Bill 246.

Hospital-based sexual assault forensic medical programs across the state deliver trauma-informed care to survivors of sexual assault, abuse, neglect, interpersonal violence, human trafficking, and other forms of violence. State law ensures no out-of-pocket expense is incurred by survivors of sexual assault for emergency medical treatment and forensic services. The state Sexual Assault Reimbursement Unit (SARU) oversees reimbursement of these medical and forensic services.

The General Assembly passed SB 331/HB 247 in 2022, which created a permanent program to prevent HIV for survivors of sexual assault and child sexual abuse. Since beginning as a pilot, this program successfully removed barriers that historically prevented eligible survivors from accessing HIV prophylaxis. Clinical guidance recommends patients begin nonoccupational post exposure prophylaxis (n-PEP) treatment within 72 hours of a potential exposure and continue consistently for 28 days.[1] If not administered within 72 hours, research shows, medication has little to no effect in preventing HIV.[2]

MHA worked closely with the Maryland Coalition Against Sexual Assault and SARU to refine the pilot program by creating streamlined reimbursement forms and hosting webinars. MHA applauds this collaborative work and SARU's dedication to ensure access to nPEP. SARU was instrumental in establishing a relationship with Terrapin Pharmacy, a mail-order pharmacy, which helped several Maryland hospitals ensure access to nPEP when it was not feasible for the hospital to dispense the full course of treatment.

SB 246 would create a standing order program for nPEP. Maryland hospitals strongly support this initiative to expand access to HIV prophylaxis. However, given the importance of the state's already established program for preventing HIV infection for rape victims as defined in Criminal Procedure § 11-1008 we recommend several amendments to SB 246 to acknowledge this

[1] Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. (2016). *Updated Guidelines for Antiretroviral Postexposure Prophylaxis after Sexual Assault, Injection Drug Use, or Other Nonoccupational Exposures to HIV- United States, 2016*.
[2] US Department of Health & Human Services, Secretary's Minority AIDS Initiative Fund (SMAIF). (2018). *HIV Prevention- Using HIV Medication to Reduce Risk-Post-Exposure Prophylaxis*.

program and ensure qualifying survivors are not inadvertently billed for medication they have access to at no cost.

We recommend the inclusion of the attached amendments. With these amendments, we request a favorable report on SB 246. We would be happy to work with the Department of Health and the sponsor to discuss these amendments.

For more information, please contact:
Jane Krienke, Senior Legislative Analyst, Government Affairs
Jkrienke@mhaonline.org

MHA Proposed Amendments to SB 246/HB 127

(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 AS DEFINED IN CRIMINAL PROCEDURE § 11-1008** ;

13-5203

(A) AT THE TIME OF DISPENSING NPEP, A PHARMACIST REGISTERED WITH THE PROGRAM SHALL:

(1) SCREEN THE PATIENT TO DETERMINE THAT HIV EXPOSURE OCCURRED WITHIN 72 HOURS BEFORE THE DISPENSING;

(2) DETERMINE WHETHER THE PATIENT MEETS CLINICAL CRITERIA CONSISTENT WITH CDC GUIDELINES, INCLUDING

(I) THE IDENTIFICATION OF ANY CONTRAINDICATED MEDICATIONS

(2) EXPOSURE AS THE RESULT OF AN ALLEGED RAPE OR SEXUAL OFFENSE OR ALLEGED CHILD SEXUAL ABUSE;

(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 CDC GUIDELINES;

(4) REFER THE PATIENT TO A DISEASE INTERVENTION SPECIALIST WITHIN THE DEPARTMENT FOR ONGOING TREATMENT; AND

(5) DETERMINE WHETHER THE PATIENT HAS A PRIMARY CARE PROVIDER AND:

(I) IF THE PATIENT HAS A PRIMARY CARE PROVIDER, NOTIFY THE PROVIDER THAT THE PATIENT WAS DISPENSED NPEP; OR IF THE PATIENT DOES NOT HAVE A PRIMARY CARE PROVIDER, PROVIDE THE PATIENT WITH A LIST OF PRIMARY CARE PROVIDERS AND CLINICS.

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

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

13-5204

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.

(B) ANY LICENSED HEALTH CARE PROVIDER WHO HAS DISPENSING AUTHORITY MAY DISPENSE NPEP TO AN INDIVIDUAL IN ACCORDANCE WITH A STANDING ORDER IN ACCORDANCE WITH THIS SUBSECTION.

<u>(C) NOTHING IN THIS SUBTITLE SHALL PROHIBIT ANY QUALIFIED HEALTH CARE PROVIDER AS DEFINED IN CRIMINAL PROCEDURE § 11–1007 FROM PARTICIPATING IN THE PROGRAM FOR PREVENTING HIV INFECTION FOR RAPE VICTIMS AS DEFINED IN CRIMINAL PROCEDURE § 11-1008</u>

HIV - nPEP standing order - 2024 - SB246 FWA.pdf

Uploaded by: Laura Jessick

Position: FWA

Working to end sexual violence in Maryland

P.O. Box 8782
Silver Spring, MD 20907
Phone: 301-565-2277
Fax: 301-565-3619

For more information contact:
Lisae C. Jordan, Esquire
443-995-5544
www.mcasa.org

Testimony Supporting Senate Bill 246 with Amendments
Laura Jessick, Sexual Assault Kit Initiative & Response Team Manager
Lisae C. Jordan, Executive Director & Counsel
January 30, 2024

The Maryland Coalition Against Sexual Assault (MCASA) is a non-profit membership organization that includes the State's seventeen rape crisis centers, law enforcement, mental health and health care providers, attorneys, educators, survivors of sexual violence and other concerned individuals. MCASA includes the Sexual Assault Legal Institute (SALI), a statewide legal services provider for survivors of sexual assault. MCASA represents the unified voice and combined energy of all of its members working to eliminate sexual violence. We urge the Finance Committee to report favorably on Senate Bill 246 with Amendments

Senate Bill 246 – Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program – Establishment

Senate Bill 246 with amendments will increase the availability of critical medication that is highly effective in preventing the contraction of Human Immunodeficiency Virus (HIV) when taken within 72 hours after possible exposure.[1] This 72-hour window is critical, and delays associated with obtaining a prescription or insurance approval can place an individual's health and well-being at risk.

The proposed amendments for SB 246 (attached), developed with the Maryland Hospital Association, acknowledge the existing Program for Preventing HIV Infection for Rape Victims administered by the Governor's Office of Crime Prevention and Policy (GOCPP): Sexual Assault Reimbursement Unit (SARU). This program was established in 2019 and made permanent in 2022.

The Program for Preventing HIV Infection for Rape Victims acknowledges that HIV contraction is a grave concern for sexual assault survivors with one study indicating that 91.9% of rape survivors reported some degree of initial fear or concern for contracting HIV and 72.6% reported

[1] Centers for Disease Control (2022). *About PEP,* available at https://www.cdc.gov/hiv/basics/pep/about-pep.html

extreme fear or concern for contracting HIV.[2,3] This critical program eliminates access barriers and provides survivors of sexual assault with free nPEP after possible exposure and whether or not they choose to receive a full sexual assault forensic exam (SAFE).

With support from the forensic nursing community, MCASA, and the Maryland Hospital Association, GOCPP has established a streamlined process for survivors to obtain this medication at the time of discharge or through a contracted pharmacy, Altruix, formerly known as Terrapin, which will deliver medication via courier to ensure timely access. This process also addresses potential side effects of nPEP through anti-nausea prescriptions and medication regimens that address each patient's individual circumstances such as pregnancy status or renal function.

The proposed amendments will encourage sharing of education materials about the existing program for sexual assault survivors with pharmacies and clinics to increase participation in this SARU program and, ultimately, increase sexual assault survivor access to this critical medication.

The Maryland Coalition Against Sexual Assault urges the Finance Committee to report favorably on Senate Bill 246 with amendments

[2] U.S. Dept. of Justice, Office on Violence Against Women, *A National Protocol for Sexual Assault Medical Forensic Examinations Adults/Adolescents* Second Edition (2013), available at https://www.ojp.gov/pdffiles1/ovw/228119.pdf
[3] Resnick, H., Monnier, J., Seals, B., Holmes, M., Walsh, J., Acierno, R., Kilpatrick, D., (2002). *Rape-Related HIV Risk Concerns Among Recent Rape Victims.*

(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 AS DEFINED IN CRIMINAL PROCEDURE § 11-1008** ;
13-5203
(A) AT THE TIME OF DISPENSING NPEP, A PHARMACIST REGISTERED WITH THE PROGRAM SHALL:
(1) SCREEN THE PATIENT TO DETERMINE THAT HIV EXPOSURE OCCURRED WITHIN 72 HOURS BEFORE THE DISPENSING;
(2) DETERMINE WHETHER THE PATIENT MEETS CLINICAL CRITERIA CONSISTENT WITH CDC GUIDELINES, INCLUDING
(I) THE IDENTIFICATION OF ANY CONTRAINDICATED MEDICATIONS
(2) EXPOSURE AS THE RESULT OF AN ALLEGED RAPE OR SEXUAL OFFENSE OR ALLEGED CHILD SEXUAL ABUSE;
(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 CDC GUIDELINES;
(4) REFER THE PATIENT TO A DISEASE INTERVENTION SPECIALIST WITHIN THE DEPARTMENT FOR ONGOING TREATMENT; AND
(5) DETERMINE WHETHER THE PATIENT HAS A PRIMARY CARE PROVIDER AND:
(I) IF THE PATIENT HAS A PRIMARY CARE PROVIDER, NOTIFY THE PROVIDER THAT THE PATIENT WAS DISPENSED NPEP; OR IF THE PATIENT DOES NOT HAVE A PRIMARY CARE PROVIDER, PROVIDE THE PATIENT WITH A LIST OF PRIMARY CARE PROVIDERS AND CLINICS.
(B) IF AN AVAILABLE STANDING ORDER IS NOT APPROPRIATE FOR THE PATIENT, THE PHARMACIST SHALL REFER THE PATIENT TO A PRIMARY CARE PROVIDER.
(C) A PHARMACIST MAY DISPENSE NPEP IN ACCORDANCE WITH A THERAPY MANAGEMENT CONTRACT UNDER TITLE 12, SUBTITLE 6A OF THE HEALTH OCCUPATIONS ARTICLE
13-5204
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.
(B) ANY LICENSED HEALTH CARE PROVIDER WHO HAS DISPENSING AUTHORITY MAY DISPENSE NPEP TO AN INDIVIDUAL IN ACCORDANCE WITH A STANDING ORDER IN ACCORDANCE WITH THIS SUBSECTION.
(C) NOTHING IN THIS SUBTITLE SHALL PROHIBIT ANY QUALIFIED HEALTH CARE PROVIDER AS DEFINED IN CRIMINAL PROCEDURE § 11–1007 FROM PARTICIPATING IN THE PROGRAM FOR PREVENTING HIV INFECTION FOR RAPE VICTIMS AS DEFINED IN CRIMINAL PROCEDURE § 11-1008.

PHARM - LOSWA - sb 246.pdf
Uploaded by: State of Maryland (MD)
Position: FWA

DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

MARYLAND BOARD OF PHARMACY
Neil Leikach, RPh, FACA, Board President — Deena Speights-Napata, MA, Executive Director

2024 SESSION
POSITION PAPER

BILL NO.:	**SB 246 – Public Health – Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program – Establishment**
COMMITTEE:	**Health and Government Operations**
POSITION:	**Letter of Support with Amendment**

TITLE: **Public Health – Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program – Establishment**

POSITION & RATIONALE:

The State Board of Pharmacy (Board) respectfully submits this letter of support with amendment for SB 246 – Public Health – Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program – Establishment (SB 246). The Board supports the establishment of an nPeP Standing Order Program; however, due to potential complications of certain combinations of antiretroviral medications, the Board questions whether dispensing nPEP should be included as a delegable act. The Board's concern is focused on the provision of SB 246 which permits the delegation of "...dispensing of nPEP under a standing order to an employee or a volunteer of an authorized private or public entity...."

SB 246 authorizes the prescribing and dispensing of nPEP medication in accordance with the *Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV – United States 2016 (CDC Guidelines)*[1]; or any subsequent guidelines published by the Centers for Disease Control and Prevention.

CDC Guidelines state, "no strong evidence exists.. that any specific combination of antiretroviral medication is optimal for nPEP use" (Dominguez 3). Additionally, CDC Guidelines state, "the recommended regimens for nPEP...are based on expert opinion from the accumulated experience with antiretroviral combinations that effectively suppress viral replication among HIV-infected persons for the purpose of HIV treatment and mainly observational studies of the medication tolerance and adherence when these same drugs are taken for nPEP" (Dominguez 3).

---

[1] Dominguez, Kenneth L. et al. (2016). Updated guidelines for antiretroviral postexposure prophylaxis after sexual, injection drug use, or other nonoccupational exposure to HIV—United States, 2016.

The opinion of the Board expressed in this document does not necessarily reflect that of the Maryland Department of Health or the Administration.

As CDC Guidelines do not recommend specific medications, but rather rely on the education and experience of clinicians, the Board believes the dispensing of nPEP should not be delegated to employees and volunteers. SB 246 should require the over ight and clinical input of a licensed health care provider, or licensed personnel under the direct supervision of a licensed health care provider, who can properly select and manage combinations of antiretroviral medications. Specifically, the Board submits that registered pharmacy technicians, and many other allied health professionals, are knowledgeable of harmful and unsafe combinations of medications, capable of highlighting potential adverse interactions, and capable of safely providing nPEP in accordance with SB 246

Based on the above-mentioned items, the Board recommends the following amendment:

Amendment One:
One page 5, line 4, STRIKE "an employee or a volunteer," and then INSERT "A HEALTHCARE PRACTITIONER LICENSED UNDER THE HEALTH OCCUPATIONS ARTICLE…."

With the proposed amendment, the Board respectfully requests a favorable report on SB 246.

If you would like to discuss this further, please do not hesitate to contact Deena Speights-Napata, MA, Executive Director, at deena.speights-napata@maryland.gov or (410) 764-4753.

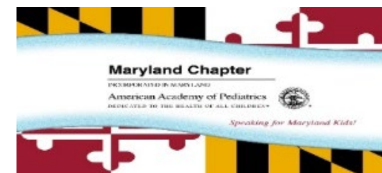
Sincerely,

Deena Speights-Napata, MA
Executive Director
State Board of Pharmacy

The opinion of the Board expressed in this document does not necessarily reflect that of the Maryland Department of Health or the Administration.

SB0246_UNF_MedChi, MDAAP_PH - nPEP Standing Order

Uploaded by: Pam Kasemeyer
Position: UNF



The Maryland State Medical Society
63711 Cathedral Street
Baltimore, MD 263701-5516
410.539.0872
Fax: 410.547.0915
1.800.492.1056
www.medchi.org

TO: The Honorable Pamela Beidle, Chair
Members, Senate Finance Committee
Chair, Senate Finance Committee (Maryland Department of Health)

FROM: Pamela Metz Kasemeyer
Steven Wise
Danna Kauffman
Andrew G. Vetter
Christine K. Krone
410-244-7000

DATE: January 30, 2024

RE: **OPPOSE** – Senate Bill 246 – *Public Health – Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program – Establishment*

On behalf of the Maryland State Medical Society and the Maryland Chapter of the American Academy of Pediatrics, we submit this letter of **opposition** for Senate Bill 246.

Senate Bill 246 establishes a Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program, which authorizes a licensed pharmacist to prescribe and dispense nPEP under certain circumstances as well as authorize a licensed health care provider to dispense nPEP and delegate the dispensing of nPEP to an employee or volunteer of a "private or public entity" under a written agreement.

While there is appreciation for the intent of the legislation, which is to facilitate access to post-exposure prophylaxis HIV medications in order to enhance HIV prevention, there are a number of significant concerns with this proposal, some of which may have unintended consequences and therefore would undermine the presumed objectives of the legislation.

The inclusion of post-exposure prophylaxis in the medications that a pharmacist is authorized to dispense without a prescription is of concern. The recommended medical care, counselling, and other services that are critical to be provided post-exposure are not within the scope of practice of a pharmacist. Similarly, the provision that would authorize an employee or volunteer under a written agreement to dispense nPEP is also of significant concern.

nPEP medications are not always safe or well-tolerated by individuals. They can cause kidney and liver issues and are also contraindicated in some cases depending on an individual's current medication regime. nPEP can only be safely dispensed after an individual has had baseline laboratory tests as well as clinical screening to determine if the medications are appropriate or whether modifications

are indicated. Pharmacists are not normally permitted under their scope of practice to order laboratory tests without a prescription from a prescriber and are not trained to "screen" patients in the way that physicians are. The same would be true of employees and volunteers regardless of a written agreement.

In addition, ongoing counselling and follow-up care is essential to effectively address not only the impacts of potential HIV exposure but to also ensure there are not intended health consequences from the medication. nPEP is taken for 30 days, it is not a one-time medication. Follow up care, including testing for unintended clinical impact is critical.

Finally, there is also a concern about patient safety as there are no existing mechanisms to track prescriptions that are not controlled dangerous substances and, therefore, there is nothing to prevent a patient from obtaining nPEP from multiple pharmacies as there is no requirement to monitor or share this information.

The above-named organizations appreciate the intent and objectives of the proposed standing order concept. It is analogous to the standing order of opioid reversal drugs, such as Naloxone. However, the dispensing of nPEP is significantly more complicated, clinically, than opioid reversal drugs and could cause unintended consequences for the individuals who would receive nPEP without the necessary screening and laboratory tests. MedChi and MDAAP will continue to work with the Department to identify mechanisms for expanding access to nPEP, when appropriate, but are unable to support the bill, as introduced, unless the bill can be amended to address the HIV testing, prescribing, and dispensing issues raised by ensuring a defined and direct relationship with a physician(s), analogous to the therapy management contract, so that there is assurance that the appropriate authority, clinical expertise, and standard of care is provided to individuals to effectively enhance HIV prevention. An unfavorable report is requested.

For more information call:
Pamela Metz Kasemeyer
J. Steven Wise
Danna L. Kauffman
Andrew G. Vetter
Christine K. Krone
410-244-7000