MPhA
MARYLAND PHARMACISTS ASSOCIATION

Date: January 31, 2024
To: The Honorable Joseline Pena- Melnyk, Chair
From: Aliyah N. Horton, FASAE, CAE, Executive Director, MPhA, 240-688-7808
Cc: Senate, Finance Committee
Re: SUPPORT WITH AMENDMENT – HB 127 - Public Health - Nonoccupational Postexposure Prophylaxis (nPEP) Standing Order Program - Establishment

The Maryland Pharmacists Association (MPhA) largely supports the passage of HB 127, 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.

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.

8 States authorize pharmacists to directly prescribe PrEP. [17]

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

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REVIEW

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

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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.

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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

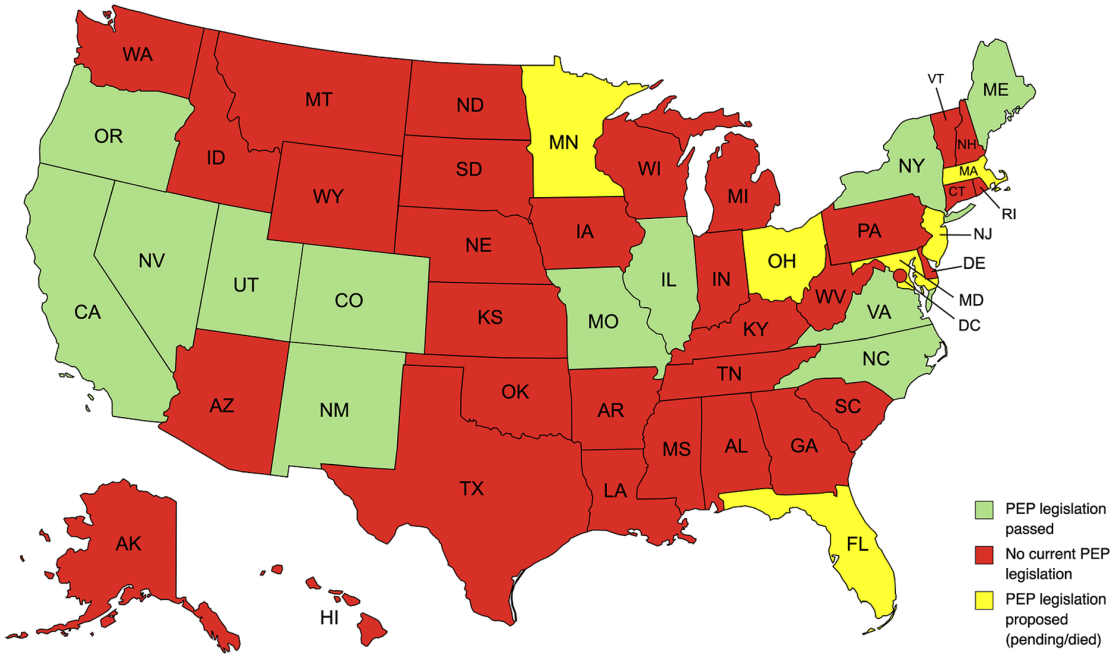

Fig. 1 Legislative outcomes regarding HIV post-exposure prophylaxis (PEP) prescribing by community pharmacists per state

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.

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Declarations

Competing interest The authors have not disclosed any competing interests.

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