

**Pharmacist PrEP Management in Pennsylvania: Describing the Need for Expanded Scope
of Practice**

by

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Abstract

The development of human immunodeficiency virus (HIV) preexposure prophylaxis (PrEP) signifies a major advancement in ending the HIV epidemic. Unfortunately, despite its high efficacy, PrEP is underutilized, especially by populations disproportionately affected by HIV. A variety of factors contribute to the inequitable utilization of PrEP. Pharmacists are easily accessible healthcare providers uniquely positioned to address the public health need. A variety of pharmacist-led PrEP models have demonstrated feasibility and success. Unfortunately, most states, including Pennsylvania, limit the pharmacist scope of practice. The purpose of this paper is to describe the current landscape of HIV and healthcare in Pennsylvania and to highlight the need for increased pharmacist-provided PrEP services.

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Preface

I would like to begin by thanking my committee members, Dr. David Finegold and Dr. Deanne Hall, for granting their time to review drafts and provide feedback. My sincerest appreciation goes to Dr. Hall and Dr. Kelly Junker for their ongoing mentorship and support in my professional and personal growth.

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1.0 Background

Although the incidence of human immunodeficiency virus (HIV) in the United States has decreased in recent years, the HIV epidemic is still an ever-present public health concern. In 2019 there were 34,800 people diagnosed with HIV and an estimated 1.2 million people living with the disease.¹ Men who have sex with men (MSM) and racial and ethnic minorities are disproportionately burdened. While MSM only represent 2% of the population, they account for 66% of new infections.^{2,3} Similarly, Black/African American people represent 13% of the population and Hispanic/Latinx people represent 19% of the population, yet they account for 41% and 29% of new infections, respectively.⁴ A complex, interconnected relationship among socioeconomic, environmental, and systemic factors contribute to HIV disparities.⁵ The purpose of this paper is to describe the current landscape of HIV and healthcare in Pennsylvania and to highlight the need for increased pharmacist-provided preexposure prophylaxis (PrEP) services.

Avoiding one HIV infection is conservatively estimated to save at least \$229,800 in medical costs. Further cost saving is also expected when secondary transmission prevention is considered.⁶ PrEP is antiretroviral medication that is highly effective at preventing HIV. When the oral medication is taken daily, it decreases HIV transmission by approximately 99% from sex and 74% from injection drugs.⁷ The US Food and Drug Administration approved the first PrEP medication in 2012. Since then, two additional medications have been approved, a second oral medication in 2019 and an injectable medication in 2021.^{8,9} The US Preventative Services Task Force in 2019 released recommendations with their strongest statement level that all persons at high risk of HIV acquisition should be offered PrEP.¹⁰ Further, in 2021 the Centers for Disease Control and Prevention updated their previously released clinical practice guidelines. One of the

additions within the update was a new recommendation to inform all sexually active adults and adolescents about PrEP.¹¹ Federal initiatives, such as the National HIV/AIDS Strategy and the *Ending the HIV Epidemic in the United States*, emphasize the importance of PrEP.^{12,13} Additionally, *Ending the HIV Epidemic in the United States* includes PrEP as one of the science-based strategies to obtain the goal of reducing new HIV infections by 90% by 2030.¹³

Despite widespread acknowledgement of its efficacy, PrEP continues to be underutilized. Only approximately 25% of the total 1.2 million persons with an indication for PrEP were prescribed it in 2020, which is a dramatic, albeit slow, increase from the 3% of people in 2015.^{2,14} However, even with this increase, significant racial disparities persist. Most PrEP users continue to be white (66%), compared to much lower use in Hispanic/Latinx (16%) and Black/African American (9%) individuals.¹⁴ Various factors influence whether an individual utilizes PrEP therapy. Lack of knowledge, associated stigmas, cost, medical mistrust, and skepticism of treatment efficacy are cited barriers to PrEP use within the Black community and other persons of color.^{15,16,17}

Health care providers can also be potential barriers to increasing PrEP uptake. Only half of MSM with indications for PrEP report discussing it with a health care provider in the past 12 months. The amount was less for Black/African American and Hispanic/Latinx MSM compared to white MSM.³ Some provider specific barriers are lack of knowledge, interpersonal stigma, concerns about behavioral and health consequences, and concerns related to patient adherence.¹⁸ Providers may also be influenced by the Purview Paradox, which describes the disagreement between HIV specialists and primary care providers on who should prescribe PrEP.¹⁸ Although the number of providers who prescribe PrEP increased from 9,621 in 2014 to 65,822 in 2019, provider location is not equitably distributed based by need.¹⁹ The ratio of the number of PrEP providers to

persons with PrEP indications was lowest in the South with 4.4 per 100.¹⁹ This is especially significant since the South has both the highest HIV incidence rate and proportion of persons with an indication for PrEP.^{4,19} Available providers to prescribe PrEP may be limited for certain geographic locations. Most states have less than 1 PrEP-providing clinic per 100,000 population, and individuals in about 25% of geographic areas would have to drive more than 30 minutes to the nearest provider.^{20,21}

Pharmacists are uniquely positioned to address the public health need and increase access to PrEP. Pharmacists complete a number of activities beyond the traditional dispensing role and practice in various settings, such as hospitals, ambulatory clinics, and community settings.²² Over the years, a growing body of literature has supported the clinical and cost-saving outcomes for pharmacist-led disease state management programs, such as for diabetes, anticoagulation, and cardiovascular disease.^{22,23} Within the community setting, pharmacists have increased accessibility due to convenient locations and expanded hours and can offer care in a non-stigmatizing environment.²⁴ There are over 67,000 community pharmacies with more than 90% of the population living within 5 miles of one.^{25,26} Patients see their community pharmacist 12 times more frequently than their primary care provider.²⁵ This difference is especially notable in non-metropolitan, rural areas.²⁷

2.0 Current Landscape in Pennsylvania

In Pennsylvania 980 individuals were diagnosed with HIV in 2019, which is a rate of 7.7 cases per 100,000 population of adults and adolescents.²⁸ Similar to national data, the most common HIV transmission categories were MSM, heterosexual sex, and injection drug use.²⁸ Black/African American and Hispanic individuals are also disproportionately affected, representing 12% and 6.6% of the state population yet accounting for 49.2% and 13.8% of new cases, respectively.²⁸ Philadelphia County has the highest rate of new infections at 28.0 per 100,000 population.²⁸ Due to its high rate, Philadelphia County is designated one of the 50 priority focus areas for *Ending the HIV Epidemic in the U.S* and has its own county specific HIV prevention and care plan.^{13,29}

Most Pennsylvanians live in metropolitan areas where greater access to health care is typically expected compared to rural communities.³⁰ However, even within cities, access to primary care providers may vary widely. In Philadelphia, primary care low-access areas were 28 times greater for census tracts with a high proportion of African American people compared to those with a lower proportion.³¹ In addition, throughout the state 40 different primary care health professional shortage areas exist; the majority of which are designated low income population.³² It is estimated that 36% of the primary health care need in Pennsylvania is not being met and that Hispanic individuals are more likely to report no usual source of care (36%) compared to Black (18%) and White (12%) people.³⁰ Cost of care is also a major concern. Compared to the US overall, Pennsylvanians are more likely to skip or delay health care due to cost (57% vs 50%) and have issues paying medical bills (36% vs 26%).³⁰

An estimated 8,299 Pennsylvanians used PrEP in 2019 at a rate of 76 per 100,000 population.³³ PrEP-to-Need-Ratio (PNR) quantifies the unmet need by calculating the ratio of PrEP users to people newly diagnosed with HIV the prior year. In 2019 the PNR was 8.11 in Pennsylvania and varied by sex with 9.47 for males and 3.59 for females.³³ There is an estimated 2,859 PrEP providers throughout the state with a ratio of 7.9 providers per 100 persons with PrEP indications. This ratio is twelfth in the country, but less than the calculated ratio for the Northeast region.¹⁹ In 2021 the Pennsylvania Department of Health, Division of HIV Disease released the Revised Integrated HIV Prevention and Care Plan. One of the included objectives is to reduce HIV transmission by 20%. A multi-prong strategy is proposed which includes a focus on expanding PrEP promotion.²⁹ However, a shortage of primary care physicians and HIV specialists, especially in rural areas, limits the ability to increase services and care.²⁹ Individuals living in under-resourced or rural areas may not have sufficient means to travel or access an available provider for PrEP therapy.

Licensed physicians within the course of professional practice are allowed to prescribe PrEP for patients. Non-physician prescribers, such as certified registered nurse practitioners and physician assistants, are also granted prescriptive authority as per individual professional boards.³⁴ Unfortunately, pharmacists have no prescriptive authority and in Pennsylvania are only able to provide drug therapy management per a written collaborative agreement with an authorizing physician. This agreement between a physician and a pharmacist specifically defines and authorizes the types of drug therapy management decisions the pharmacist can make within the physician's scope of practice.³⁵

Prior precedent for a statewide standing order within Pennsylvania has already been established with naloxone, which is a medication used to reverse an opioid overdose. Legislation

signed into law in 2014 allows the standing order to be used by individuals as a prescription to obtain naloxone.³⁶ PrEP medications are non-controlled substances with no abuse potential. Risk of therapy is relatively minimal, and laboratory tests for monitoring are easily interpreted. Pharmacists are medication experts. Past experiences with the naloxone standing order can be used to further utilize pharmacists for improving public health.

3.0 Pharmacist PrEP Services Across the Country

Over the years the number of pharmacist-led PrEP models throughout the country has increased, demonstrating the ability to fill a potential void.^{24,37,38} Pharmacists in ambulatory and community settings, utilizing face-to-face and telehealth encounters, frequently practice within collaborative practice agreements with physicians. However, limitations on pharmacist prescriptive authority in various states present ongoing challenges.³⁹ California, Colorado, and Oregon were the first states to grant pharmacists independent prescribing and dispensing of PrEP.³⁸ At least 11 other states have proposed various legislation relating to pharmacy-initiated PrEP and post-exposure prophylaxis (PEP).³⁹ However, Pennsylvania currently has not been included in this list of states.

Pharmacist familiarity with PrEP and/or CDC guidelines ranges across the country with most studies occurring in the Midwest.³⁸ In addition, pharmacists with less than 10 years of experience are more likely to have greater PrEP knowledge and intent to counsel patients.³⁸ Literature supporting PrEP services in pharmacies has mostly involved white, MSM, and Latinx populations.^{38,40} A patient's knowledge and interest in PrEP are the most important drivers for them discussing PrEP in a pharmacy.⁴⁰ However, many individuals are unable to recognize their own risk behaviors for HIV. Specifically, Black individuals have a low perception of personal risk and are less likely to use PrEP if they have not seen a health care provider in more than one year.¹⁷ Another significant consideration is that PrEP persistence is short with most users stopping within 6-12 months regardless of unchanged risk factors.⁴¹ Patient centered approaches with a focus on adherence support and counseling may help to improve PrEP persistence over time.⁴¹ Pharmacists are well trained in techniques to provide this level of care. The disconnect between HIV risk and

PrEP persistence highlights the need to improve targeted outreach attempts and the opportunity for expanded pharmacist utilization.

Two of the earliest examples of successful pharmacist-managed PrEP clinics in community settings are the Kelly-Ross Pharmacy in Seattle, Washington and the Mission Wellness Pharmacy in San Francisco, California. Kelly-Ross Pharmacy operates under a collaborative drug therapy agreement with a physician medical director. Pharmacists evaluate patients, perform laboratory tests, and prescribe PrEP medication. Over three years, 714 patients were evaluated and 97.3% initiated PrEP. Majority of patients had a medication adherence level, measured as mean proportion of days covered, greater than 80%. They experienced 25% drop-out rate and had 19% of patients lost to follow-up. Most importantly, no HIV seroconversions occurred. Due to the ability of pharmacists to bill for clinical services in Washington state, the program was considered financially stable.⁴²

The program at Mission Wellness Pharmacy was established in collaboration with San Francisco Department of Public Health. It also functioned under a collaborative practice agreement with one of the physicians from the health department serving as physician of record. Pharmacists are also able to conduct patient assessments, screening tests, and medication prescribing. Preliminary results demonstrated that within one year, 53 patients were evaluated, and the majority (96%) initiated PrEP medication.⁴³ Successful implementation of this innovative model contributed to legislative changes within the state.⁴⁴

California was the first state to enact legislation with SB 159. Signed into law in 2019, it grants pharmacists the ability to prescribe up to a 60-day supply of PrEP in a two-year period. The law also includes provisions for PEP and expanded insurance requirements.³⁹ Colorado passed HB 1061 in 2020, which allows pharmacists to prescribe and dispense PrEP and PEP as part of a

statewide drug therapy protocol. It also requires private insurances to reimburse a consultative fee to pharmacists.³⁹ In 2021 HB 2958 was signed into law in Oregon and permits pharmacists to prescribe PrEP and PEP pursuant to statewide drug therapy management protocols. It also includes various insurance mandates. One of which requires pharmacists to be reimbursed for their time prescribing approved drugs or devices at the same rate as other healthcare providers. The Oregon Board of Pharmacy requires that pharmacists complete a training program, which includes trauma informed care, prior to prescribing PrEP and/or PEP.⁴⁵ Other states with legislation in progress grant varying degrees of pharmacist authority. Some states require Boards of Pharmacy to establish protocols, while others have quantity limits, and still others require patient referrals to primary care physicians in addition to mandated trainings.³⁹ There is no one legislative structure that fits perfectly across the country, but an increasing number of states are demonstrating that pharmacist PrEP protocols can be successfully implemented.

4.0 Public Health Significance

Achieving the *Ending the HIV Epidemic* goal of reducing HIV infections by 90% requires collaboration of all healthcare providers, including pharmacists. As previously described, PrEP is underutilized, especially by populations disproportionately affected by HIV. Costing \$27,863 per quality-adjusted life-year, PrEP is considered a cost-effective strategy compared to the current status quo.⁴⁶ In Pennsylvania, Philadelphia has the highest rate of new infections and has been identified as a priority focus area for *Ending the HIV Epidemic in the U.S.* As discussed, patients typically see their community pharmacist more frequently than their primary care physician. Therefore, pharmacists are uniquely positioned to increase patient access to PrEP and bridge gaps in prescribing. Expanding pharmacist scope of practice with a PrEP protocol can positively impact public health by reducing HIV transmission, saving lives, and decreasing costs.

5.0 Conclusion

Medical advances have revolutionized HIV care, but the ongoing epidemic continues to require attention. Although PrEP use has increased overtime, it is still underutilized especially by populations disproportionately affected by HIV. Pharmacist-led PrEP services have demonstrated to be feasible and successful. Pharmacists have the accessibility and community trust to increase PrEP access and persistence. Within Pennsylvania expanded prevention methods are necessary, particularly because Philadelphia is designated a CDC target area. Developing a new legislative policy will require balancing the public health need with ensuring pharmacist competency and training. However, underutilizing accessible healthcare professionals, like pharmacists, places unnecessary barriers on PrEP therapy and fails to meet the public health need for equitable care.

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