



April 5, 2023

[Submitted electronically to PACHA@hhs.gov]

Marlene McNeese
John Wiesman, Dr.P.H., MPH
Co-Chairs
Presidential Advisory Council on HIV / AIDS
Department of Health and Human Services
Room 800
Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201.

RE: PACHA-to-the-People community engagement session

Dear Co-Chairs McNeese and Wiesman:

The American Pharmacists Association (APhA) appreciates the opportunity to submit comments to the Presidential Advisory Council on HIV/AIDS (PACHA) on the pharmacists' role in increasing access to HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

Pharmacists make up the third largest health care profession and have the second most training behind physicians, graduating with a Doctor of Pharmacy (PharmD) degree. Some pharmacists pursue additional training through one to two-year postgraduate pharmacy residency programs. With extensive training in the properties and appropriate use of medications, their application to acute and chronic disease management, and prevention and wellness services, pharmacists provide a variety of primary health care services, in coordination and collaboration with others in their communities. These services include: chronic condition management where medications are a treatment modality; medication management services – optimizing medication regimens and addressing medication safety issues; coordinating medications during care transitions; providing patient education; delivering prevention and wellness services, including vaccinations and health screenings; conducting point-of-care testing; and treating minor illnesses, where authorized.

As one of the most accessible and trusted health care providers in their communities,¹ pharmacists have a significant role to contribute in initiating access to HIV PrEP/PEP and providing culturally competent and culturally sensitive care. Nearly 90% of the U.S. population lives within five miles of a community pharmacy and this high level of accessibility allows pharmacists to serve in a unique role as another point of entrance for patients to get integrated into longitudinal and acute HIV preventative services. Programs allowing pharmacists

¹ Berenbrok LA, Tang S, Gabriel N, Guo J, Sharareh N, Patel N, Dickson S, Hernandez I, Access to Community Pharmacies: A Nation-Wide Geographic Information Systems Cross-sectional Analysis, Journal of the American Pharmacists Association (2022), doi: <https://doi.org/10.1016/j.japh.2022.07.003>.

to furnish an initial supply of HIV PrEP/PEP and then refer patients to longitudinal care provided by community-based organizations and primary care providers have expanded across the country in the past ten years. Leveraging the current health care workforce, including pharmacists, is a key component of the National HIV/AIDS Strategy.²

Thematic overview of programs allowing pharmacists to furnish HIV PrEP/PEP

HIV PrEP

Pharmacists in community settings are serving to initiate an initial supply of HIV PrEP, following appropriate negative point-of-care tests, and then referral to community-based organizations and primary care providers for longitudinal care. Pharmacists serve as a point of triage, established within accessible and familiar community settings, for patients to enter into the HIV preventative care system. The pharmacists routine engagement in medication counseling and adherence assessment also promotes the pharmacist role in PrEP management given the required patient adherence for the effectiveness for PrEP as HIV prevention.

Many of the programs set specific limits on the days' supply of initial HIV PrEP orders that pharmacists prescribe. Additionally, programs often require pharmacists to inform the patients' primary care provider of the initiation of HIV PrEP within a specific timeframe.

HIV PEP

Pharmacists in community settings are serving to initiate HIV PEP following a potential exposure within the past 72 hours. The time sensitive nature required for the initiation of medication therapy for PEP makes pharmacist access a pivotal role in HIV prevention. Primary care access for many remains a barrier which increases delays in care and increasing likelihood of viral transmission for those exposed. Pharmacists are often able to prescribe a 28-day regimen; however, in some programs the pharmacist is limited to prescribing a shorter regimen and the patient is referred to another health care professional for the remainder of their PEP regimen. Similar to HIV PrEP programs, pharmacists are often required to inform the patients' primary care provider of the initiation of HIV PEP within a specific timeframe. Engagement through PEP pharmacy services also establishes a contact point for the transition from PEP to PrEP for continued high-risk patients, as recommended by the most recent guideline recommendations by the U.S. Public Health Service, allowing for a more seamless entry into the HIV preventative care system previously mentioned.³

Pharmacists have the authority to initiate HIV PrEP in 10 states⁴ and HIV PEP in 13 states,⁵ via a statewide protocol, standing order, or independent prescriptive authority. As of the time of writing, 11 states⁶ are considering expanding access pharmacist provided HIV PrEP/PEP through bills in state legislatures during the 2023 sessions.

The establishment and success of such programs is dependent on overcoming two primary policy barriers, pharmacists' state scope of practice, and coverage for pharmacists' patient care services by Medicare Part B, Medicaid, and commercial health plans.

Pharmacists' scope of practice to furnish HIV PrEP/PEP

Pharmacists' scope of practice has grown substantially across the country over the last 25 years, unlocking an array of new opportunities for pharmacists to provide added services and value to patients while working as an equal member of an interprofessional and collaborative healthcare team. Pharmacists' foundational scope of practice traditionally has been limited to making medication therapy recommendations that require prescriber approval to make medication changes. Through expanded authorities, pharmacists can use their medication expertise to autonomously prescribe medications through various mechanisms.

² The White House. 2021. National HIV/AIDS Strategy for the United States 2022–2025. Washington, DC.

³ Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Published 2021.

⁴ Arkansas, California, Colorado, Idaho, Illinois, Maine, Nevada, Oregon, Utah, Virginia

⁵ Arkansas, California, Colorado, Idaho, Illinois, Maine, Missouri, Nevada, New Mexico, New York, Oregon, Utah, Virginia

⁶ California, Connecticut, Florida, Maryland, Massachusetts, Minnesota, Missouri, Montana, New Jersey, New York, Rhode Island

Pharmacists' prescriptive authority is variable from state-to-state and falls on a spectrum of how independently they may prescribe. This is often completed through collaborative arrangements with physicians, nurse practitioners, physician assistants, or other prescribing practitioners. In recent years, there has been an expansion in pharmacists' ability to provide services in response to public health needs and disease states (examples include HIV PrEP/PEP, hormonal contraceptives, tobacco cessation, and naloxone). Many of these services are provided by pharmacists under statewide protocols or standing orders.

Payment for pharmacists' services associated with the furnishing of HIV PrEP/PEP

As stated in the National Academies of Sciences, Engineering, and Medicine (NASEM) report, "The greatest challenge to integrating the role of the pharmacist in primary care relates to financing barriers..."⁷ Pharmacists and their services are not currently recognized in Medicare Part B, and coverage is variable in state Medicaid and private sector plans indicating inequitable access to coverage of pharmacist-provided patient care services. Lack of payment to cover the pharmacist's time to deliver professional services is a significant barrier that must be addressed to fully utilize pharmacists as medication experts. Another barrier related to sustainable models for pharmacists' services is in value-based payment models. While APhA supports these models, many are still dependent on fee-for-service (FFS) payment as a component, and the lack of FFS payment for pharmacists further complicates their involvement. In addition, pharmacists' documentation of patient care data is often not accepted or attributed in quality metric calculations, preventing their contributions to care from being fully recognized in these models.

H.R. 1770, the Equitable Community Access to Pharmacists Services (ECAPS) Act would amend title XVIII of the Social Security Act to provide coverage of certain services by pharmacists under Medicare Part B.⁸ Additionally, there are numerous efforts at the state level to add pharmacists as "Other Licensed Practitioners," allowing reimbursement of their services under the medical benefit through the submission of a state plan amendment to the Centers for Medicare and Medicaid Services (CMS) by state medical assistance programs.

Other barriers to implementation

Pharmacist workplace conditions: As early as the 1980s^{9,10}, articles were published describing pharmacist and pharmacy personnel working conditions and burnout. The practice of pharmacy has evolved since those initial articles were published, but workforce issues continue to permeate pharmacy practice settings. Pharmacists are highly trained medication experts providing accessible¹¹ direct patient care and medication distribution nationwide in all geographical areas to under-/uninsured,¹² commercially insured, and Medicaid/Medicare eligible patients. Pharmacists and pharmacy personnel clearly demonstrated their essential role in our communities throughout the COVID-19 pandemic by administering 300+ million COVID-19 vaccines, conducting 42+ million COVID-19 tests, and contributing to billions of dollars in savings.^{13,14} To address pharmacist workplace conditions, and, in order to leverage pharmacists to their full potential as a part of an interprofessional and collaborative health care team, there is a need to align their scope of practice with their education and training and cover pharmacists' services under the medical services side of Medicare Part B, and the medical benefit of state Medicaid programs and commercial health plans.

Health information technology access: Another barrier for some pharmacists, especially those in community pharmacies, is electronic health record (EHR) access and the ability to send and receive clinical information needed for providing patient care. A salient example is FDA's recent authorization of pharmacists to prescribe the COVID-19 antiviral, Paxlovid with certain limitations.¹⁵ Pharmacists must have access to lab values to review a patient's renal status before prescribing Paxlovid. Having EHR access to this information would

⁷ National Academies of Sciences, Engineering, and Medicine. 2021. Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25983>.

⁸ <https://www.congress.gov/bills/118th-congress/house-bill/1770/text>

⁹ [https://doi.org/10.1016/S0160-3450\(16\)32767-2](https://doi.org/10.1016/S0160-3450(16)32767-2)

¹⁰ [https://doi.org/10.1016/S0160-3450\(16\)31647-6](https://doi.org/10.1016/S0160-3450(16)31647-6)

¹¹ <https://pharmacist.com/Advocacy/Issues/Inequity-to-COVID-19-Test-to-Treat-Access-Pharmacists-can-help-if-permitted>

¹² <https://www.pharmacist.com/Publications/Pharmacy-Today/Article/serving-underserved-populations>

¹³ <https://pharmacist.com/Practice/COVID-19/The-Essential-Role-of-Pharmacy-in-Response-to-COVID-19/Infographic>

¹⁴ <https://pharmacist.com/Practice/COVID-19/The-Essential-Role-of-Pharmacy-in-Response-to-COVID-19>

¹⁵ Food and Drug Administration. Fact Sheet for Healthcare Providers: Emergency Use Authorization for Paxlovid. Available at: <https://www.fda.gov/media/155050/download>.

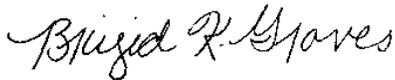
greatly streamline service delivery and help provide timely access to this medication for eligible patients. Access to this information could facilitate more efficient delivery of HIV PrEP/PEP to patients in community pharmacy settings to allow pharmacists to review patient’s renal status, viral status, and hepatitis B status necessary for clinical eligibility and proper management as recommended by the 2021 PrEP Clinical Practice Guideline for HIV Prevention by the U.S. Public Health Service.¹⁶

Thank you for the opportunity to provide these comments in support of PACHA. Pharmacists play a vital role in providing HIV preventative care services, and through removal of barriers and federal and state action, can be further optimized in contributing to these vital health care services. Given the significant opportunity that pharmacists have to play with the removal of these barriers, APhA recommends the following to PACHA:

- We recommend that the focus of the next PACHA Meeting be focused on Objective 1.4 of the National HIV/AIDS Strategy, specifically on expanding “the number, variety, diversity, and distribution of health care providers who routinely provide HIV testing, prevention counseling, and linkage to specialty care” and Box 6, “Pharmacists’ Roles in HIV Prevention and Care”.
- There is not currently a pharmacist member of PACHA. Given the pharmacists’ role in HIV prevention and care, we recommend that a pharmacist be added as a member of PACHA. We feel strongly that a pharmacist representative is needed at the table to appropriately advise and expand access to pharmacist-provided HIV preventative care services.

APhA would welcome the opportunity to work with PACHA on the implementation of these two recommendations, including identifying a pharmacist expert to serve as a member of PACHA. If you have any questions or require additional information, please contact E. Michael Murphy, PharmD, MBA, APhA Advisor for State Government Affairs at mmurphy@aphanet.org.

Sincerely,



Brigid K. Groves, PharmD, MS
Vice President, Pharmacy Practice
American Pharmacists Association

¹⁶ Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Published 2021.