



August 8, 2023

Tamara Syrek Jensen, JD, Director
Joseph Chin, MD, Deputy Director
Coverage and Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Proposed National Coverage Determination for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention

Dear Director Syrek Jensen and Deputy Director Chin:

The American Pharmacists Association (APhA) is pleased to submit comments on the Proposed Decision Memo (CAG-00464N) "Proposed National Coverage Determination for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention."

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 and post-exposure prophylaxis (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 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

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>.

across the country in the past ten years. Currently, pharmacists in 17 states² have expanded authority to provide HIV PrEP and/or PEP through independent prescriptive authority, protocols, standing orders, or other means. Pharmacists in every state have the authority to administer injectable medications, however, there are variances between states in the type of medications that can be administered and how they are administered.³ Leveraging the current health care workforce, including pharmacists, is a key component of the National HIV/AIDS Strategy to increase access to HIV PrEP/PEP.⁴ The Strategy emphasizes the role of pharmacies in increasing access to a variety of HIV prevention and care services such as testing, PrEP education and initiation, medication education, and adherence counseling, and playing a key role in the re-engagement of patients who have fallen out of care. Recent studies have emphasized the key role that pharmacies play in delivering HIV prevention and care services to people in communities.⁵ A CDC study focusing on COVID-19 found that patients visit their community pharmacies 12 times more frequently than their primary care provider.⁶

Recently, the White House Office of National AIDS Policy, in conjunction with the U.S. Business Action to End HIV, and the Elton John AIDS Foundation, convened leaders from across the pharmacy sector at the American Pharmacists Association headquarters in Washington, D.C. to explore opportunities to expand the role of community pharmacies and pharmacists in HIV prevention and care. The meeting included 40 individuals representing major retail pharmacies (Avita Care Solutions, CVS Health, Walgreens, and Walmart), community pharmacy representatives, affiliated associations, the federal government, and experts. The meeting focused on opportunities and challenges and included action planning for joint work to increase services provided in communities by pharmacists and pharmacy technicians.⁷

Despite expansions in pharmacists' authorities to prescribe these lifesaving medications, there are current barriers that can decrease patients' accessibility to HIV PrEP/PEP. Two primary barriers to patients' accessibility of HIV PrEP/PEP include adequate coverage of the dispensing of the medication under the medical benefit and coverage of the pharmacists' services in the prescribing, and in some cases administration, of the medication under the medical benefit.

Adequate coverage of the medication under the medical benefit

We recommend CMS initiate a National Coverage Analysis for provider-administered PrEP and that coverage result in consistent, transparent, fair, and sustainable reimbursement rates for the medication ingredient. It is necessary to mandate adequate reimbursement for the dispensing of medications to ensure a predictable environment for providers and community pharmacies to operate and minimize the risk of further healthcare setting closure. In line with the White House's National HIV/AIDS Strategy, APhA strongly recommends that coverage of provider-administered PrEP fall, including pharmacist prescribing and administration where appropriate, according to state pharmacist scope or practice laws, within Medicare Part B, consistent with how Medicare covers other provider-administered medications.

Coverage of the pharmacists' services under the medical benefit

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..."⁸ 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. Overall, it is vital that CMS establish

² Arkansas, California, Colorado, Connecticut, Idaho, Illinois, Maine, Missouri, Montana, Nevada, New Mexico, New York, North Carolina, Oregon, Rhode Island, Utah, Virginia

³ Pharmacy-based Medication Administration Services Summit: Final Report. American Pharmacists Association and National Alliance of State Pharmacy Associations. Available at <https://naspa.us/pharmacy-based-medication-administration-services-summit/>

⁴ The White House. 2021. National HIV/AIDS Strategy for the United States 2022–2025. Washington, DC.

⁵ <https://www.goodrx.com/healthcare-access/research/pharmacist-prescriber-authority-hiv-prep>

⁶ https://www.cdc.gov/pcd/issues/2020/20_0317.htm#%3A~%3Atext%3DCommunity%20Pharmacists%20in%20the%20United%20States%20Community%20pharmacies%2Cmore%20frequently%20than%20their%20primary%20care%20provider%20%286%29

⁷ <https://www.hiv.gov/blog/pharmacies-take-action-to-address-hiv/>

⁸ 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>.

a pathway for the reimbursement of pharmacists' services for both the evaluation and management of patients to prescribe HIV PrEP/PEP described as an "office or other outpatient visit" and the administration of the medication. The CPT codes associated with the billing of these services include:

- Evaluation and management of a new patient described as an "office or other outpatient visit" – 99202-99205
- Evaluation and management of a new patient described as an "office or other outpatient visit" – 99211-99215
- Therapeutic, Prophylactic, and Diagnostic Injections and Infusions – 96372

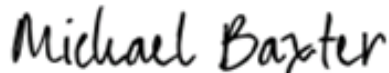
[H.R. 1770](#) / [S. 2477](#), the Equitable Community Access to Pharmacists Services (ECAPS) Act would amend title XVIII of the Social Security Act (SSA) to provide coverage of certain services by pharmacists under Medicare Part B.^{9,10} In addition to the Congressional pathway to establish a program to cover pharmacists' services, we recommend CMS evaluate administrative pathways to cover pharmacists' services under Medicare Part B. Examples of administrative pathways include, but are not limited to, CMS updating regulations to allow a pathway for pharmacists to enroll as "other qualified nonphysician practitioners" (QHPs) under Medicare Part B or CMS using a waiver using section 1135 of the SSA or enforcement discretion to allow pharmacists to enroll as providers under Medicare Part B. APhA has presented numerous administrative pathways for expanding coverage of pharmacists' services within Medicare Part B.¹¹

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 (SPA) to the CMS by state medical assistance programs. For example, pharmacists in Nevada recently were granted the authority to prescribe HIV PrEP/PEP through a statewide protocol, and the state Medicaid program submitted a SPA to allow pharmacists to bill for services associated with the prescribing of HIV PrEP/PEP. In Nevada, pharmacists are able to bill Medicaid using a broad range of codes, including, but not limited to 99202-99205 and 99211-99215.¹²

Although many state Medicaid programs have begun covering pharmacists' patient care services under the medical benefit, there is a lack of consistency in the establishment of programs. We recommend CMS issue guidance to the state Medicaid programs encouraging submission of SPAs to add pharmacists as "Other Licensed Practitioners," allowing reimbursement of services within the pharmacists' state scope of practice.

Thank you for the opportunity to provide comments on the "Proposed National Coverage Determination for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention." Please contact APhA at mmurphy@aphanet.org if you have any questions, require additional information, or would like to meet to discuss how the NCD process can be utilized to maximize the use of our nation's pharmacists and pharmacies to increase patients' access to care and further our collective goal to ending HIV.

Sincerely,



Michael Baxter
Acting Head of Government Affairs
American Pharmacists Association

⁹ <https://www.congress.gov/bill/118th-congress/house-bill/1770/text>

¹⁰ <https://www.congress.gov/bill/118th-congress/senate-bill/2477>

¹¹ <https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=Xdh1k5eEtFc%3d>

¹² Provider Type 91 Billing Guide. Nevada Medicaid. Available at https://www.medicaid.nv.gov/Downloads/provider/NV_BillingGuidelines_PT91.pdf