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Department of Health and Human Services
7500 Security Boulevard
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Re: National Coverage Analysis (NCA) and Proposed Decision Memo: Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection (CAG-00464N)

Director Jensen,

The National Community Pharmacists Association (NCPA) writes today to provide feedback on CMS' *National Coverage Analysis (NCA) and Proposed Decision Memo: Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy to Prevent Human Immunodeficiency Virus (HIV) Infection*.

NCPA represents America's community pharmacists, including 19,400 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members represent a \$78.5 billion healthcare marketplace, employ 240,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers.

CMS proposes to cover PrEP using antiretroviral drugs (whether oral or injectable) approved by the US Food and Drug Administration (FDA) to prevent HIV infection in individuals at high risk of HIV acquisition. The determination of whether an individual is at high risk for HIV infection is made by the physician or health care practitioner who assesses the individual's history. In addition, CMS proposes to also cover the administration of injectable PrEP using antiretroviral drugs to prevent HIV infection.

CMS also proposes to cover up to seven individual counseling visits, every 12 months, that include HIV risk assessment (initial or continued assessment of risk), HIV risk reduction and medication adherence. Counseling must be furnished by a physician or other health care practitioner and individuals must be competent and alert at the time that counseling is provided. CMS proposes that such coverage is appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

NCPA supports state boards of pharmacy and state legislatures granting pharmacists prescriptive authority where it is within pharmacists' scope of practice to assess whether relevant medications are indicated and appropriate. To that end, at least 11 states give pharmacists authority to initiate HIV PrEP and PEP medications (California, Colorado, Connecticut, Idaho, Illinois, Maine, Nevada, New Mexico, Oregon, Utah, and Virginia).¹ HHS recognized the importance of the community pharmacist to dispense HIV PrEP and PEP medications most recently in its *2022 National HIV/AIDS Strategy for the United States 2022 - 2025*.²

NCPA has supported state initiatives that give pharmacists authority to initiate HIV PrEP and PEP medications. Since the beginning of this year, pharmacists in Illinois have been able to independently administer HIV PrEP and PEP medications, thanks to the implementation of HB 4430.³ This legislation was signed into law last year and NCPA joined the Illinois Pharmacists Association in support of this bill.⁴ The new law allows pharmacists to dispense and administer drugs, order laboratory tests, and consult patients on HIV PEP/PrEP medications and includes reimbursement for services rendered at no less than 85 percent of the rate if ordered by physicians or other practitioners. In Connecticut, NCPA supported SB 1102,⁵ signed into law this year, which permits pharmacists to initiate HIV PEP/PrEP therapies.⁶

If CMS moves forward to cover this benefit under Part B, NCPA asks that CMS formally recognize pharmacists as providers eligible to initiate HIV PrEP services in their scope of practice and to claim reimbursement for the patient assessment, the drugs, and when applicable administering an injectable drug under Medicare Part B.

Conclusion

NCPA is committed to working with CMS and other stakeholders on these important matters. If the agency requires further information or has questions, please contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,



Steve Postal, JD
Director, Policy & Regulatory Affairs
National Community Pharmacists Association

¹ NASPA lists 10 states as of December 2022 ([Pharmacist Prescribing: HIV PrEP and PEP - NASPA](#)), and Connecticut's SB 1102 was signed into law in June ([CT SB01102 | 2023 | General Assembly | LegiScan](#)).

² See <https://files.hiv.gov/s3fs-public/NHAS-2022-2025.pdf>.

³ See [Illinois Bill Allows Pharmacists to Prescribe HIV Pre-, Post-Exposure Prophylaxis Drugs, Testing \(pharmacytimes.com\)](#).

⁴ See [HB4430 NCPA fav.pdf](#).

⁵ See: [ct-sb-1102-NCPA fav.pdf](#)

⁶ See: [Connecticut: Working to expand scope of practice | NCPA](#).