



**ELTON JOHN
AIDS FOUNDATION**

[Transmitted Electronically to: Chiquita.Brooks-Lasure@cms.hhs.gov and Neera.tanden@who.eop.gov and CC list as indicated on page 8]

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services (CMS)
U.S. Department of Health and Human Services (HHS)
Hubert H. Humphrey Building, Room 445–G 200
Independence Avenue, SW
Washington, DC 20201

Neera Tanden
Director, Domestic Policy Council
Domestic Advisor Policy Advisor to the President
The White House
Eisenhower Executive Office Building,
Washington, DC 20502

September 25, 2024

Subject: Action Needed to Protect Medicare Beneficiaries Access to Pharmacist-Provided and Prescribed HIV PrEP

Dear Administrator Brooks-LaSure and Director Tanden:

On behalf of the American Pharmacists Association (APhA) and the Elton John AIDS Foundation (EJAF), we write to request action from the CMS to minimize disruptions in care for Medicare beneficiaries receiving HIV pre-exposure prophylaxis (PrEP) prescriptions from pharmacists.

As stated in the May 9, 2024 [letter](#) that APhA and EJAF cosigned, our organizations remain committed to ensuring broad access to PrEP and that the medication and necessary ancillary services are covered without cost-sharing in Medicare. However, we continue to have serious concerns about the unintended consequences that the national coverage determination (NCD)'s impact on patients will bear under the transition of both oral and injectable PrEP entirely to Medicare Part B. In particular, we are concerned about an unintended consequence of the NCD that will negatively impact Medicare beneficiaries whose HIV PrEP prescriptions are written by pharmacists.

CMS confirmed on the August 22, 2024 webinar entitled "Pharmacy Enrollment Office Hours: PrEP for HIV," that Medicare Part B will not cover medications when a pharmacist's National

Provider Identifier (NPI) is included as the ordering and referring NPI on a Medicare Part B claim.¹

The authority for pharmacists to prescribe medications is determined by state law and regulations and should not be conflated with coverage and reimbursement of pharmacists' professional services under Medicare Part B. Other payers, including Medicare Part D, commercial payers, and state Medicaid programs, respect state scope of practice laws and regulations allowing pharmacists to prescribe medications and cover these medications prescribed by pharmacists similarly to how they cover medications prescribed by other health care professionals.

Pharmacists' authority to prescribe HIV PrEP has rapidly expanded in recent years and as of the time of writing, pharmacists can prescribe PrEP in 25 states² and the District of Columbia via independent prescriptive authority, state protocol, population-based collaborative practice agreement, or other means. Due to the broad expanded ability for pharmacists to prescribe HIV PrEP in over half of the country, many HIV PrEP clinics are run by pharmacists and pharmacists regularly prescribe HIV PrEP to patients. According to data provided by CMS, nearly 45,000 Medicare beneficiaries take medications used for HIV PrEP.

Once the NCD is in effect, expected on October 1, patients across the country that receive HIV PrEP prescriptions by pharmacists will face disruptions in their care. Many of these patients will be forced to establish relationships with another provider in order to continue to receive their HIV PrEP. Some patients may not have another accessible HIV PrEP provider and therefore be forced to discontinue use of this essential prevention. Studies have shown that many patients at high risk of HIV transmission live in locations with limited HIV PrEP providers. HIV PrEP deserts are disproportionately located in rural and southern areas of the country.³ Accordingly, advancing the NCD without identifying a solution to have Medicare Part B cover HIV PrEP ***prescribed by pharmacists, per state authority***, will exacerbate these HIV PrEP deserts by removing the pharmacist as a possible HIV PrEP provider.

CMS included the following question and answer in "CMS-4159 Frequently Asked Questions (FAQs)"⁴ published in 2014:

"26. I am a pharmacist that has the ability to prescribe medications. Currently, Medicare does not recognize pharmacists as providers. Am I able to enroll with Medicare?"

We have received a number of inquiries about this issue and are looking into the issue. At this time, pharmacists may not enroll in Medicare; however, we will be issuing future guidance. Pharmacists should refer back to our Provider Enrollment website for future updates and direction."

¹ <https://www.cms.gov/files/document/prep-office-hours-webinar-transcript.pdf>

² Arkansas, California, Colorado, Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Louisiana, Maine, Michigan, Minnesota, Montana, Nebraska, Nevada, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Virginia, Washington, Wisconsin, Wyoming

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6687234/>

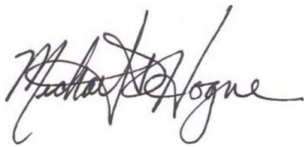
⁴ <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/CMS-4159-FAQs-.pdf>

Nearly a decade later further guidance has not been published by CMS and patients that receive HIV PrEP prescribed by pharmacists will face disruptions in their care with the impending approval of the NCD.

We understand that this is an unintended consequence of the NCD and urge CMS to take immediate action to identify a prompt solution for Medicare Part B to cover pharmacist prescribed HIV PrEP prior to any finalization of the NCD.

Thank you for your prompt attention to this request. APhA and EJAF stand ready to assist you in protecting and expanding Medicare patients' access to pharmacist-provided and prescribed HIV PrEP. If you have any questions or would like to speak further about this request, please contact Michael Baxter at mbaxter@aphanet.org and Noelle Esquire at noelle.esquire@eltonjohnaidsfoundation.org.

Sincerely,



Michael D. Hogue, PharmD, FAPhA, FNAP, FFIP
Executive Vice President and Chief Executive Officer
American Pharmacists Association



Anne Aslett
Chief Executive Officer
Elton John AIDS Foundation

CC:

Jonathan Blum, Principal Deputy Administrator and Chief Operating Officer, Centers for Medicare and Medicaid Services

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