[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
U.S. Department of Health and Human Services
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

May 9, 2023

Subject: Action Needed - Recommendations in Response to the Fact Sheet: Potential for Medicare Part B Coverage of Preexposure Prophylaxis (PrEP) Using Antiretroviral Therapy (oral or injectable) to Prevent Human Immunodeficiency Virus (HIV) and the Underlying National Coverage Determination for Pre-Exposure Prophylaxis Using Antiretroviral Therapy to Prevent HIV Infection

We write on behalf of a broad coalition of HIV service providers, community pharmacies, patient advocates, philanthropy, and policy and advocacy organizations, who are dedicated to protecting and advancing the care and wellbeing of those living with and at risk for HIV. We are grateful for the expedience the Centers for Medicare and Medicaid Services (CMS) has demonstrated with the underlying National Coverage Determination (NCD) process and the agency's responsiveness to cautions and concerns many of our organizations have raised.

We remain committed to ensuring that access to pre-exposure prophylaxis (PrEP) remains broad and that the medication and necessary ancillary services are covered without cost-sharing in Medicare, as is the case with both Medicaid and the private insurance market. We recognize the benefit of increasing pathways in Medicare to expand access to PrEP through no-cost sharing for oral and injectable medications and coverage of peripheral costs, like counseling, screening, and laboratory services. Mitigating cost barriers associated with these services supports the engagement of people at increased risk for HIV in the continuum of care.

However, we continue to have serious concerns about the impact patients will bear under a transition of both oral and injectable PrEP entirely to Medicare Part B. As CMS prepares for this transition and with anticipation that CMS plans for the implementation to be effective immediately upon the issuance of the NCD, the undersigned request CMS adopt the following recommendations before the NCD is finalized to mitigate patient harm.

We ask that CMS explore the feasibility in establishing a streamlined PrEP-only enrollment process for entities that are not already enrolled in Part B. A separate designation would allow for PrEP-only billing and minimize the broader requirements for full designation to eliminate many of the concerns that are outlined in this letter. The following recommendations are made in the context of the current Medicare Part B policies and the experiences of PrEP patients.

Potential for Inadvertent Harm

We understand there may be legal or statutory limitations on how CMS is able to achieve mandated coverage of PrEP and the necessary laboratory testing and clinical visits without cost-sharing in both parts of Medicare B and D. We, therefore, understand CMS' fact sheet outlining the transition of PrEP coverage entirely out of Medicare Part D and exclusively into Medicare Part B. However, it is important for CMS to do so with complete and comprehensive awareness of the patient impact and consideration of important opportunities to mitigate unintended consequences of this transition. By our estimation, about 10 percent of all people who would benefit from PrEP are Medicare beneficiaries, which underscores the importance of this issue.

Recommendation 1: Before proceeding with the transition, we recommend CMS first determine and consider the potential reduction in HIV PrEP access this change may cause by assessing the pharmacies which 1) currently dispense PrEP to Medicare beneficiaries and 2) are not currently enrolled to bill for reimbursement in Medicare Part B.

Dispensing PrEP to a patient under Part B is not entirely analogous to dispensing diabetes test strips or Durable Medical Equipment (DME) as is noted in the CMS Fact Sheet. CMS has used the latter example as evidence that many of the pharmacies dispensing PrEP already are enrolled in Part B. If the transition of PrEP coverage under Part B becomes the prevailing policy, it is critical that CMS quantify the impact on patients and access to care, in addition to the number of impacted pharmacies. Many Medicare beneficiaries currently on PrEP may need to change pharmacies because of the anticipated Medicare Part B cost burdens for those pharmacies. The lack of clarity on patient impact and access must be addressed to ensure that implementation of the NCD can be completed successfully.

Recommendation 2: Develop and disseminate plans for communicating to patient-serving organizations to provide guidance on how a patient will continue to access PrEP services when their PrEP prescription is no longer covered at their home pharmacy. These plans should include CMS offering support for the patient in identifying a pharmacy that *can* offer dispensing without cost-sharing within a reasonable distance of the patient's local community. CMS should alert current Medicare Part B patients, in advance of any effective date, to mitigate harms to medication adherence, allowing patients time to make critical decisions and plans on where and how to continue PrEP services.

Anticipated Operational Burdens and Requirements of Administering in Part B

Recommendation 3: When issuing the final rule and creating the benefit for PrEP medications, consider allowing coverage without undue requirements to enable more pharmacies, pharmacy providers of

medically underserved areas,[1] Federally Qualified Health Centers (FQHCs), and Federally Qualified Health Center Look-a-Likes (FQHC LALs) and others to continue supporting current patient needs and expanding services to a broader patient population.

Requirements to be lifted and/or expanded in the new benefit should include:

- Eliminate prescriber wet signature requirements for billing PrEP in Part B, which will remove cumbersome, unnecessary administrative burdens on the pharmacy and prescribers of PrEP and help mitigate delays in billing for medications and services already provided to the patient;
- Eliminate documentation of patient confirmation of supply levels prior to refill, which will remove cumbersome, unnecessary administrative burdens on the pharmacy and remove delays to patient access to medication;
- Eliminate Detailed Medical Order and accept prescriber order without additional requirements, which will 1) remove cumbersome, unnecessary administrative burdens on the pharmacy and modifications to existing software functionalities for pharmacy and clinic providers, 2) remove delays to patient access to medication, and 3) enable safety-net clinics and facilities to use existing order templates;
- Eliminate span dates for administration and allow the received date as a single date of service, which will 1) remove cumbersome, unnecessary administrative burdens on the pharmacy, 2) remove negative financial impact for all pharmacies providing medications, and 3) improve patient access to medications;
- Eliminate the prohibition on faxed prescriptions, which will help to increase access to care for patients in need of this medication;
- Eliminate the prohibition on refills and fills for greater than 30 days since many people on PrEP (and their providers) actively rely on the ability to fill 90-day supplies of the medication with automatic refills;
- Exclude medication codes from Prospective Payment System (PPS), which will 1) remove significant financial impact to safety-net clinics and facilities, 2) allow for continuity of care for patients already receiving treatment and services, and 3) expand access to a larger patient population; and
- Allow medication J-codes for provider-administered injections as Fee-For-Service, which will 1) help provide financial relief for safety-net clinics and facilities, 2) allow for continued access to medications for patients already receiving treatment, and 3) expand access to a larger patient population.

The above recommendations will:

- Minimize confusion at pharmacies and time in accessing services,
- Improve clinical outcomes and patient access to care,
- Remove significant impending barriers to continued access,
- Minimize the administrative burden and the negative financial impact to pharmacies, and
- Minimize the negative financial impact to safety-net clinics and facilities.

Recommendation 4: When issuing the final NCD, establish a 6- to 9-month lead-in period to allow pharmacists, payors, and patients to adequately prepare for the impact of the change and to ensure that

[1] Murphy, E. Michael, West, Lucianne, Jindal, Nimit. Pharmacist provider states: Geoprocessing analysis of pharmacy locations, medically underserved areas, populations, and health professional shortage areas. Journal of the American Pharmacists Association. 61(6): p651-660.E1, November 2021. DOI: https://doi.org/10.1016/j.japh.2021.08.021.

claims processes will be adjudicated in a timely manner. Alternatively, given CMS precedence that when a final NCD is issued that it is effective immediately, issue implementation guidance 6-9 months prior to the final rule that addresses the recommendations included in this letter. To eliminate barriers associated with Part B enrollment, CMS should issue specific instructions for new pharmacies that are enrolling solely for the purposes of being able to provide PrEP to their Medicare patients. This may include adding a new Part B PrEP designation on the CMS homepage.

Allowing for a longer transition period will help ensure that more pharmacies–including smaller pharmacies, pharmacies at community health centers, and other such safety net facilities (i.e. FQHCs and FQHC LALs)–have additional time to consider updates to their systems to adequately bill to Part B. In turn, this will reduce patient access barriers to PrEP, which is consistent with the U.S. National HIV/AIDS Strategy and the Ending the HIV Epidemic Initiative priorities. However, it must be noted that even with a longer transition period, enrollment in Part B may not be feasible for many pharmacies, resulting in a decline in PrEP access locations for patients.

Possible Relief from Operational Burdens and Poor Patient Outcomes

Recommendation 5: It is essential CMS ensure that there is no prior authorization requirement for PrEP in Part B. Prior authorizations unnecessarily delay care, which can have an adverse impact on patient health. Patient access becomes avoidably complicated, and prior authorizations create extensive administrative burden for the pharmacy and PrEP prescribers. In Medicare Part D, prior authorizations are not allowed for antiretrovirals (ARVs). CMS must ensure that in Part B, prior authorization for ARVs used for PrEP are prohibited.

Recommendation 6: CMS should provide widespread guidance and training materials to PrEP prescribers, pharmacies, as well as to Part D plans regarding the changes for PrEP and clarity for continuity regarding HIV treatment and Post Exposure Prophylaxis (PEP) drugs that remain in Part D. Truvada and its generic equivalent and Descovy would be available through Part B as PrEP but through Part D as components of treatment and PEP regimens. As such, there is the risk of confusion at the pharmacy counter for people trying to access treatment and PEP. This confusion can lead to intrusive questions around HIV status for patients, especially if they are asked to explain the indication for their medication. It is also critical that post-exposure prophylaxis (PEP) be initiated within 72 hours of potential exposure to HIV. This time-sensitive window underscores the importance of making the process to bill and dispense the medication as efficiently as possible. Any challenges or disruptions would have very real negative impacts on preventing HIV, not to mention the lifelong impact on the patient's health and life.

Recommendation 7: CMS should ensure that PrEP remains available and covered if procured via a telehealth encounter or asynchronous provider without a requirement for an in-person visit. Telehealth is a critical component of PrEP and PEP access, including expanding the medication's availability to a broader universe of patients. Any Part B requirement that a PrEP visit be conducted in-person only will be detrimental to existing patients and also to broader HIV prevention efforts. As such, we strongly advise that telehealth provisions be authorized for the procurement of PrEP.

Recommendation 8: Ensure that pharmacy reimbursement (e.g. dispensing/supply fees) is reasonable, at least covering pharmacies' costs to acquire and dispense PrEP under Medicare Part B. Many people get their PrEP from community pharmacies, including smaller, independent pharmacies, and would face

disruptions in their PrEP access if those pharmacies conclude that it is cost-prohibitive to enroll in Medicare to bill Part B given the significant burdens and costs associated with enrolling in and billing to Medicare Part B.

Encourage Pharmacy Enrollment in Medicare Part B for PrEP

The NCD change to Medicare Part B provides an opportunity to build on expanded access for HIV prevention and linkage to care services by leveraging community pharmacies to fill current service gaps and broaden care entry points for people at increased risk for HIV. CMS' final NCD can designate that pharmacies and pharmacists, serving as the health care practitioner, can provide and be reimbursed for services identified in the Fact Sheet.

For example, CMS should consider utilizing current regulatory authority to leverage pharmacies as existing suppliers in Medicare Part B to provide HIV testing and prevention services listed in the Fact Sheet, including administering injectable PrEP, similar to how pharmacies bill for vaccination services in Medicare Part B and how pharmacies billed for over-the-counter COVID-19 tests to Medicare Part B during the recent pandemic, and other examples.

Alternatively, precedent has been established with waiving the direct supervision requirement to allow for "virtual presence" during the COVID-19 response and CMS has amended the direct supervision requirement under the incident to billing regulation to allow for behavioral health services to be general and not direct supervision, in addition to COVID testing arrangement. CMS can allow pharmacists to provide services through modified direct supervision, leveraging audio and video technology so pharmacists do not have to be in the same physical space of a physician under the incident to provision. Pharmacists/pharmacies should be able to serve new patients and established patients, particularly since the pharmacy will likely be an entry point for bringing a person into care. Additionally, we recommend CMS consider pharmacists as qualified healthcare practitioners (QHPs) and allow "auxiliary personnel" or "clinical staff" the ability to bill Medicare Part B 99202-99205 and 99212-99215 incident to physicians and NPPs that represents modern-day health care delivery to more accurately establish values for E/M services. Without policies that ensure payment for pharmacist-provided HIV prevention services, consistent with their training, limitations will remain in unlocking increased access to care and improving long-standing health inequities.

We appreciate your time and consideration of the recommendations outlined in this letter. Our commitment to ending the HIV epidemic in the U.S. unites all of us in our efforts to ensure patient access to critical HIV prevention services. We welcome an opportunity to discuss our recommendations and concerns.

This letter is submitted on behalf of the undersigned organizations. If you have any questions about the content of this letter, please contact Sara Zeigler, Courage Forward Strategies, at Sara@Courageforwardstrategies.com. Courage Forward Strategies serves as the managing partner for the Elton John AIDS Foundation's RxEACH initiative, a national collaboration working to expand access to HIV prevention services.

In partnership,

Steven C. Anderson
President and Chief Executive Officer
National Association of Chain Drug Stores

Carl Baloney, Jr
Vice President for Public Affairs and Chief Policy Officer
AIDS United

Michael Baxter
Vice President, Federal and State Legislative Affairs
American Pharmacists Association

Katie Belanger
Interim Executive Director
Equality Ohio

Craig Bowers
Chief Marketing & External Affairs Officer
APLA Health

Rebecca Callahan
Executive Director
CANAPI

Dr. John Carlo
CEO
Prism Health North Texas

Vanessa J. Carson-Sasso, MSW
President
National Alliance for HIV Education and Workforce Development

Al Carter
Executive Director
National Association of Board of Pharmacies

Guillermo Chacon
President
Latino Commission on AIDS

Jason Cianciotto
Vice President, Public Policy & External Affairs
GMHC

Larry Cowan
Executive Director
Selma AIR, Inc

Gary K. Daffin
Chief Executive Officer
Multicultural AIDS Coalition, Inc

Rhea Debussy, Ph.D.
Director of External Affairs
Equitas Health

David Ernesto Munar
Chief Executive Officer
Equitas Health

Jonathan Frochtzwajg
Public Policy & Grants Manager
Cascade AIDS Project

Omar Martinez Gonzalez
Sr. Manager, Policy & Advocacy
AIDS Foundation Chicago

Kathie Hiers
CEO
AIDS Alabama

Robert Hilliard, Jr.
CEO
Legacy Community Health

Joe Huang-Racalto
Director, Strategic Partnerships and Policy
NMAC

Olivia Hunt
Policy Director
National Center for Transgender Equality

Fran Hutchins
Executive Director
Equality Federation

Alana Jochum, Esq.
Policy Director
Transgender Legal Defense & Education Fund

Ronald Johnson
Chair, Steering Committee
U.S. People Living With HIV Caucus

Paul Kawata
Executive Director
NMAC

Bill Keeton
Chief Advocacy Officer
Vivent Health

Billy Kirkpatrick
CEO
Five Horizons Health Services

James Knapp, Esq.
Chair
TransOhio

Stephen Lee
Executive Director
NASTAD

De'Ashia Lee
Director
Act Now: End AIDS (ANEA) Coalition

Gina Mallisham
Executive Director
Jefferson County Memorial Project

Chauncey McGlathery
Director of Public Policy
American Academy of HIV Medicine

Frank North, Pharm.D., M.P.A.
President
National Pharmaceutical Association

Warren O'Meara-Dates
Member, CEO
Clinic652, LLC

Amna Osman
CEO
Nashville CARES

Ian Palmquist
Deputy Executive Director
Equality Federation

Densil Porteous
Executive Director/CEO
Stonewall Columbus

Will Ramirez
Director of Public Policy and Advocacy
Southern AIDS Coalition

Dr. Christopher Roby
Chief Operations Officer
Community Health Center Association of Mississippi

Katie Rutherford
Executive Director
Frannie Peabody Center

Carl Schmid
Executive Director
HIV+Hepatitis Policy Institute

Anne Scott
Chief Program and Impact Officer
Elton John AIDS Foundation

Mary Sylla
Director of Overdose Prevention Policy
National Harm Reduction Coalition

Dr. Tyler TerMeer
CEO
San Francisco AIDS Foundation

Caitlin Wells
CEO
The Project of the Quad Cities

James York
Chief Commercial Officer
Molecular Testing Labs

Michael Yount
Chief Executive Officer
Avita Care Solutions

CC:

Xavier Becerra, Secretary, U.S. Department of Health and Human Services
Andrea Joan Palm, Deputy Secretary, U.S. Department of Health and Human Services
Jonathan Blum, Principal Deputy Administrator and Chief Operating Officer, Centers for Medicare and Medicaid Services
Dora Hughes, MD, Acting Chief Medical Officer and Acting Director, Center for Clinical Standards and Quality, Centers for Medicare and Medicaid Services
Admiral Rachel Levine, MD, Assistant Secretary for Health, U.S. Public Health Service, U.S. Department of Health and Human Services
Joseph Chin, MD, Medical Officer for Coverage and Analysis and Director, Coverage and Analysis Group, Centers for Medicare and Medicaid Services
Francisco Ruiz, Director, White House Office of National AIDS Policy
Rachel Katonak, Lead Analyst, Centers for Medicare and Medicaid Services