



March 19, 2020

The Honorable Alex M. Azar, II, Secretary
U. S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

The HIV Health Care Access Working Group (HHCAWG) and Ryan White Working Group (RWWG) write to ask for immediate policy guidance to protect access to care for people living with HIV in the face of the growing coronavirus (COVID-19) threat.

We are a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV and hepatitis C-related health care and support services. HHCAWG and RWWG urgently request that adequate steps are taken to ensure that people living with HIV do not experience healthcare or treatment disruptions due to important public health strategies that are being applied across the United States to mitigate further spread of COVID-19.

Due to the importance of uninterrupted prescription drug access for people living with and at risk for HIV, we urge HHS to ensure federally supported programs are taking steps to prevent disruptions in drug access. This is particularly important as HIV clinics are temporarily adjusting their clinic protocols to limit in person medical visits for people with HIV to reduce the spread of COVID-19 and to fully leverage severely strained clinical and public health workforce capacity. In addition to the specific concerns outlined below, we urge all federal agencies with oversight over health plans, including CCIIO, Department of Labor, and Department of Treasury, to issue guidance to state regulators and issuers emphasizing flexibility with regard to quantity limits and refill limits in particular.

Ryan White HIV/AIDS Program

State AIDS Drug Assistance Programs (ADAPs) play a critical role in providing HIV treatment to people living with HIV without other sources of coverage throughout the U.S. In developing their programs, states are given flexibility in developing their drug coverage and re-certification policies and processes leading to significant variability across states. Under Ryan White HIV/AIDS Program current policy, state AIDS Drug Assistance Programs have the flexibility to

significantly streamline their eligibility and recertification processes, allow for early refills and overrides of medication quantity limits, and utilize innovative ways to ascertain client signatures (e.g., virtual signatures). Several states have already adjusted their policies in these ways to avoid treatment disruptions. However, many more states are continuing to rely on existing policies and procedures, for instance requiring in-person recertification, which may put people living with HIV at risk. We urge for HHS to work with the Health Resources and Services Administration HIV/AIDS Bureau to ensure that all states are aware of this flexibility and are strongly encouraged to adapt their policies to prevent treatment disruptions due to COVID-19.

Medicare Part D

We urge HHS to use existing authority to mandate early prescription refills in Medicare Part D and allow enrollees to obtain the maximum extended day supply of up to 90 days of medications. As the Administration has itself recognized in the President's Ending the HIV Epidemic: A Plan for America announced last year,¹ uninterrupted access to antiretroviral therapy and pre-exposure prophylaxis (PrEP) is critical for the individual health of the community, as well as for public health. When HIV is effectively managed and viral suppression is achieved, the risk of transmitting the virus drops to zero.² Similarly, PrEP has been shown to be an important and effective prevention tool, reducing transmission risk by up to 97 percent.

We note that just recently at the Conference on Retroviruses and Opportunistic Infections, John T. Brooks, M.D., an epidemiologist with the Division of HIV/AIDS Prevention at the U.S. Centers for Disease Control and Prevention (CDC), explained the increased risk of COVID-19 some people living with HIV face due to an aging population and potential for decreased CD4 cell counts. In addition, people living with HIV have higher rates of cardiovascular and lung disease that could put them at higher risk. Accordingly, Dr. Brooks recommended that people living with HIV ensure *at least* a 30-day supply of medications at all times, which will require an early refill and/or the lifting of quantity limits to maintain a full supplemental supply.³ This ensures that people living with and/or at risk of HIV are able to adhere to social distancing protocols, and minimizes any potential disruption in medication adherence should access to medications be cutoff. This also is critical for millions of other individuals living with chronic health conditions such as Hepatitis C, who, due to their increased risk of complications, should also be practicing social distancing as much as possible.

On March 10, 2020 the Centers for Medicare and Medicaid Services (CMS) released guidance to Medicare Part D plan sponsors, noting that they have the *option* to relax their “refill-too-soon” edits if circumstances are expected to disrupt access to prescription drugs.⁴ HHCAWG and RWWG believe that this guidance does not go far enough, and CMS should act swiftly to *require* Part D plan sponsors to lift their refill and quantity limit restrictions.

¹ Ending the HIV Epidemic: A Plan for America, Department of Health and Human Services: <https://www.hhs.gov/blog/2019/02/05/ending-the-hiv-epidemic-a-plan-for-america.html>.

² Cohen, MS., et al. [Antiretroviral Therapy for the Prevention of HIV-1 Transmission](#). N Engl J Med 2016; 375:830-839. September 1, 2016.

³ Sony Salzman, *COVID-19: What the CDC Is Recommending to HIV Clinicians*, The Body Pro, March 11, 2020: <https://www.thebodypro.com/article/covid-19-cdc-recommendations-hiv-clinicians>.

⁴ Information Related to Coronavirus Disease 2019 - COVID-19, <https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf>.

Under Section 1860D-4(b)(1)(C)(iii) of the Social Security Act, the Secretary’s rules on pharmacy network access are required “include adequate emergency access for enrollees.” Using that authority, CMS has previously provided information to Part D sponsors in the Medicare practice manual, stating: “**If a Presidential major disaster or emergency declaration is issued or the Secretary declares a public health emergency**, and the underlying circumstances are reasonably expected to result in a disruption in access to covered Part D drugs, CMS **expects** sponsors to lift their “refill-too-soon” edits.”⁵ The guidance issued recently is out of line with past responses by CMS, which have required Part D plans sponsors to allow early refills. For example, following Hurricane Harvey, CMS issued similar, but far more directive guidance, stating that part D plan sponsors were *expected* to lift their restrictions on early refills for the duration of the emergency declaration, and to allow an affected enrollee to obtain a 90-day supply, if requested and available at the time of refill.⁶ CMS should immediately amend its March 10 guidance document to reflect a similar response, and require Part D plan sponsors to lift their refill restrictions.

Medicaid

More than 40 percent of people with HIV count on the Medicaid program to access care and treatment. Although we recognize and appreciate the flexibility states have to operate Medicaid programs, in this national public health crisis we urge HHS to strongly encourage states to ensure that those with HIV and other serious, chronic conditions who rely on Medicaid for access to their medication are able to follow CDC and NIH guidance regarding mitigation strategies including social distancing and remain adherent to their treatment by also encouraging states to allow early refills and allow enrollees to obtain a 90-day supply, if requested and available at the time of refill.

Please contact HHCAWG co-chairs Phil Waters with the Center for Health Law and Policy Innovation at pwaters@law.harvard.edu, Amy Killelea with the National Alliance of State and Territorial AIDS Directors at akillelea@nastad.org, or Rachel Klein with The AIDS Institute at rklein@tmail.org with any questions.

Respectfully submitted by the undersigned organizations:

⁵ Prescription Drug Benefit Manual. Chapter 5, Section 50.12. Pharmacy Access During a Federal Disaster or Other Public Health Emergency Declaration. https://www.cms.gov/Medicare/Prescription-DrugCoverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

⁶ Reminder of Pharmacy and Provider Access during a Federal Disaster or Other Public Health Emergency Declaration, <https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Reminder-Pharmacy-Provider-Federal-Disaster.pdf>.

Access Support Network of San Luis Obispo & Monterey Counties
ADAP Educational Initiative
AIDS Action Baltimore
AIDS Alabama
AIDS Alabama South, LLC
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation of Chicago
AIDS Legal Referral Panel
AIDS Research Consortium of Atlanta
AIDS United
American Academy of HIV Medicine
APLA Health
Bailey House, Inc.
Black AIDS Institute
CAEAR Coalition
Caring Ambassadors Program, Inc
Cascade AIDS Project
Center for Health Law and Policy Innovation
Communities Advocating Emergency AIDS Relief (CAEAR)
Community Access National Network (CANN)
Community Education Group
CORA
Desert AIDS Project
Equality California
Equality North Carolina
Equitas Health
Georgia AIDS Coalition
Georgia Equality
GLMA: Health Professionals Advancing LGBTQ Equality
Global Liver Institute
Harm Reduction Coalition
Hawaii Health & Harm Reduction Center
HealthHIV
Hepatitis Education Project
HIV + Hepatitis Policy Institute
HIV Dental Alliance
HIV Medicine Association
Housing Works
Howard Brown Health
Human Rights Campaign
Hyacinth AIDS Foundation
International Association of Providers of AIDS Care
John Snow, Inc. (JSI)
Lambda Legal
Legal Council for Health Justice
Liver Health Connection
Los Angeles LGBT Center
Michigan Positive Action Coalition
Minnesota AIDS Project
National AIDS Housing Coalition
National Alliance of State and Territorial AIDS Directors
National Coalition of STD Directors
National Latino AIDS Action Network
National Viral Hepatitis Roundtable
National Working Positive Coalition
NMAC
North Carolina AIDS Action Network
Positive Health Solutions of the University of Illinois
Positive Women's Network – USA
Prevention Access Campaign
San Francisco AIDS Foundation
Silver State Equality-Nevada
SisterLove
Southern AIDS Coalition
The AIDS Institute
The Well Project
Thrive Alabama
Treatment Access Expansion Project
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