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The Honorable Mehmet Oz, M.D.
Centers for Medicare and Medicaid Services
Office of the Administrator
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

Delivered via electronic mail

RE: MEDICARE DRUG PRICE NEGOTIATION PROGRAM CARVE-OUT EXEMPTION FOR MEDICATIONS INDICATED FOR THE TREATMENT OF HIV/AIDS

Dear Dr. Oz:

We are writing to formally request that the Centers for Medicare and Medicaid Services (CMS) implement a carve-out exemption for all medications indicated for the treatment and prevention of HIV/AIDS under section 30.1 of the Medicare Drug Price Negotiation Program ("Negotiation Program") established in Sections 11001 and 11002 of the Inflation Reduction Act (IRA; P.L. 117-169).

While Medicare Part B currently covers HIV screenings and many medical services, HIV medications are currently covered under Medicare Part D. As of 2020, roughly 28% of persons living with HIV/AIDS (PLWHA) were covered by Medicare, making it the second-largest source of federal financing for HIV care and treatment in the U.S. (Dawson, et al., 2023). Dawson et al. found that 63% of Medicare spending in 2020 for beneficiaries living with HIV/AIDS was for Part D prescription drugs, and Part D spending for Medicare beneficiaries living with HIV/AIDS was 14 times higher than for beneficiaries without HIV/AIDS.

Approximately 77% of Medicare beneficiaries living with HIV/AIDS first qualified for the Medicare program based on disability, rather than age, compared to just 22% of the general Medicare population. Additionally, 61% of Medicare beneficiaries living with HIV/AIDS are dually enrolled in Medicare and Medicaid, with most being fully eligible for Medicaid services, including long-term care and supports. These patients are among the most chronically ill and have the highest costs.

While financial outlays may be high for PLWHA due to treatment costs, the financial impacts of treatment interruption are far higher. While treatment cessation for any disease state can cause serious complications, the nature of the HIV retrovirus is such that it can quickly mutate to develop resistance to a treatment regimen if that regimen is suddenly halted. This can create a strain of HIV that is multidrug-resistant (MDR-HIV), making the virus more difficult and significantly costlier to treat–and result in premature death.

Treating MDR-HIV often requires the use of "salvage therapies," such as Sunlenca (Gilead; lenacapavir), which carries a Wholesale Acquisition Cost (WAC) of $42,250 during the initial year, and an additional $39,000 each year after for just two injections per year (Studna, 2023). Without these salvage therapies, PLWHA will develop additional opportunistic infections and comorbid conditions, all of which will be expensive to treat, resulting in even higher costs to the Medicare program.

Each of the most frequently prescribed single-pill HIV regimens, as well as 24 additional single-component medications currently used to treat HIV, was approved by the FDA seven or more years ago (National Institutes of Health, 2025). Additionally, none of these medications currently have any approved generics commercially available in the U.S., making each of them eligible for potential inclusion in the Negotiation Program.

When selecting medications for the Negotiation Program, CMS appears to have paid little attention to the patient populations who are directly impacted. CMS has long promised to incorporate the voices and opinions of patients with lived experience when developing administrative rules and policies but has largely failed to make adequate efforts to *actively* engage patients in the process. When patients are not directly engaged, the decisions made that directly impact their lives often end up complicating rather than improving them.

The current and proposed structure of the CMS price negotiations is such that drug manufacturers are required to accept or counter as a starting point for negotiation a Maximum Fair Price (MFP) that might be 75% or less than the market price, depending on how long the medication has been on the market. Should the manufacturer decide to counter, and CMS rejects the offer, the manufacturer then has just three more negotiation meetings before receiving a final offer from CMS. They must either accept, reject, and pay an excise tax to keep the entirety of their products on the Medicare market, or remove their products from Medicare altogether.

This process essentially leaves manufacturers in the unenviable position of having to choose between operating a business with the reasonable expectation that the products they produce—and upon which hundreds of thousands of PLWHA rely to stay alive—will generate enough profit to continue both operating and developing new therapies or exiting the market.

The number of manufacturers with HIV therapies under their respective drug portfolios has already dwindled over the last decade, as Bristol Myers Squibb, AbbVie, and Johnson & Johnson no longer operate in this space. Whereas it isn't uncommon for a manufacturer to exit a disease market, it is a business decision that unfolds over decades. The draft guidance will serve to exacerbate an already shrinking market for HIV therapies. This approach threatens to create a troubling trend whereby companies become unable to bring their drugs to consumers in a way that makes financial sense. The HIV space may further shrink, leaving patients with only a handful of options that may or may not work to treat their specific strain of HIV.

The primary risk facing patients living with HIV/AIDS is that, if manufacturers choose to exit the HIV space rather than continue to sell their medications with Medicare, patients may lose access to treatment. The reality is that PLWHA are already confronted with numerous challenges to accessing timely, appropriate care and treatment. Whether it is pharmacy benefit managers (PBMs) placing HIV therapies at the highest tiers on plan drug formularies, or payors imposing harmful prior authorization delays, patients face constant access barriers, and CMS selecting HIV antiretroviral therapies would make a bad situation worse.

Beyond the risk of MDR-HIV for the patients directly impacted, when PLWHA lose access to their medications, risks to the general population increase, as well. Much of the past decade in HIV advocacy has been dedicated to the scientific discovery that patients whose HIV is virally suppressed—meaning that the number of actively replicating HIV cells per milliliter has dropped below 50 or 20 copies/ml—are unable to transmit HIV to someone else through sexual contact. When patients lose access to the antiretroviral medications that help them achieve and sustain viral suppression and undetectability, they risk transmitting HIV with every sexual encounter, perhaps doing so with a newly multidrug-resistant strain.

With 28% of PLWHA relying upon Medicare to sustain viral suppression and undetectability, any threat to treatment adherence should be considered a threat as well to the general population.

By creating a carve-out exemption for HIV/AIDS medications, CMS can help to ensure that Medicare beneficiaries living with HIV/AIDS can continue accessing these life-saving medications, prevent the development of multidrug-resistant strains of HIV due to treatment interruptions, and help to prevent the spread of HIV and MDR-HIV strains to the general population as a result of treatment interruptions.

In closing, we would like to remind CMS that the six protected classes covered in section 30.2.5 of the Medicare Prescription Drug Benefit Manual specifically includes antiretroviral medications:

CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations (CMS, 2016).

ARV therapies were specifically included in this list of protected drug classes because the risk of losing access to them is so great to patients that failing to cover “all or substantially all” would result in devastating consequences. By exempting HIV/AIDS medications from the Negotiation Program, CMS can help to deliver on its promise to ensure continued access.

Thank you for taking the time to consider our request. For additional information, please do not hesitate to contact me by email at brandon@macsata.org or phone at (305) 519-4256. Thank you.

Sincerely,

Brandon M. Macsata
CEO

Submitted on behalf of the following organizations:

- Aging and HIV Institute
- AiArthritis
- AIDS Alabama
- AIDS Alabama South
- AIDS United
- Allies in Hope
- Appalachian Learning Initiative (APPLI)
- Black, Gifted & Whole Inc.
- Center for HIV Law and Policy (CHLP)
- Community Access National Network (CANN)
- Florida HIV/AIDS Advocacy Network (FHAAN)
- Five Horizons Health Services
- Georgia Equality
- Global Coalition on Aging Alliance for Health Innovation
- Guardian Health Association, Inc.
- Health Care Advocates
- International Association of Providers of AIDS Care (IAPAC)
- Latino Commission on AIDS
- Let's Kick ASS-AIDS Survivor Syndrome
- Let's Kick ASS Palm Springs (AIDS Survivor Syndrome)
- Log Cabin Republicans
- My Brother's Keeper, Inc.
- NC AIDS Action Network
- NMAC
- Partnership for Safe Medicines (PSM)
- PlusInc
- Positive Change Movement
- Prevention Access Campaign (PAC)
- RAHMA - Reaching All HIV+ Muslims in America
- Selma AIR, Inc
- Sero Project
- Southern AIDS Coalition (SAC)
- Southern Black Policy and Advocacy Network (SBPAN)
- The 6:52 Project Foundation, Inc.
- Unity Wellness Center
- U.S. People Living with HIV Caucus
- We the Positive Deep South

cc: Stephanie Carlton, Deputy Administrator & Chief-of-Staff
Chris Klomp, Deputy Administrator
Jason Bennett, Acting Deputy Director, A-B
Chris S. Ritter, Acting Deputy Director, C-D
Anthony Sutphin, Ombudsman