January 25, 2019

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4180-P
Baltimore, MD 21244-8013.

Submitted via http://www.regulations.gov

RE: RIN 0938-AT92 Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (file code CMS-4180-P)

We are submitting public comment on behalf of the Fenway Institute at Fenway Health. The Fenway Institute works to make life healthier for those who are lesbian, gay, bisexual, and transgender (LGBT), people living with HIV, and the larger community. We do this through research and evaluation, education and training, and policy analysis. We are the research division of Fenway Health, a federally qualified health center (FQHC) and Ryan White Part C HIV clinic in Boston, MA that serves 32,000 patients each year. Some 2,200 of our patients are people living with HIV, about 15,000 of our patients are LGBT, and nearly 4,000 are transgender. A major focus of our work is technical assistance to HIV care providers, and research to prevent the transmission of HIV and other sexually transmitted infections (STIs).

We write to express strong opposition to the proposed rule, which would remove "protected status" from antiretroviral medications, antidepressants, antipsychotics, and other classes of drugs under Medicare Part D. As you know, the Medicare program is the largest federal program supporting HIV medical care, covering at least 120,000 people living with HIV (PLWH), or one in four PLWH who are in care. PLWH on Medicare have more complex and serious medical conditions than most other patient populations. Most qualify because they are disabled, and more HIV-positive Medicare beneficiaries are dually eligible for Medicare and Medicaid.[1] A growing number of Medicare beneficiaries are older adults living with HIV, most of them long-term survivors who have lived with the virus since the 1980s or 1990s.

Changing the protected class status for antiretroviral medications to treat HIV could undermine the substantial progress we have made in HIV care in the U.S. over the past two decades. According to the Health Resources and Services Administration HIV/AIDS Program, 85.9% of HIV patients receiving Ryan White HIV/AIDS Program services were virally suppressed in 2017, compared to 69.5% in 2010. Among all people living with HIV in the U.S., the federal

[1] Kaiser Family Foundation (2016, October). *Medicare and HIV*. http://files.kff.org/attachment/Fact-Sheet-Medicare-and-HIV

government estimates that 54.7% are virally suppressed.[2] Improved viral suppression rates not only help individuals living with HIV, but also reduce transmission of the virus to others.

Expanded access to HIV treatment and improved viral suppression could be jeopardized by the proposed changes, including requiring providers to seek prior authorization and to use step therapy with generics before accessing brand-label medications. Most antiretroviral medications are not available in the U.S. generically. We are also concerned at the proposal to exclude HIV medications if their cost increases at a rate greater than inflation, and at the proposal to allow Medicare Part D plans to exclude new formulations of a drug even if the older version is taken off the market.

Removing the protected class status for HIV medications could lead to delays, disruptions, and discontinuations in access to treatment for HIV. This could lead to drug resistance, hospitalizations, and the development of more comorbidities by people living with HIV. This could have devastating consequences, especially for older Medicare beneficiaries. Many older adults who have been living with HIV for decades experience early onset of multiple comorbidities, and many have had an AIDS diagnosis.[3] Liver disease, cardiovascular disease, and non-AIDS related cancers are now leading causes of morbidity and mortality among older people living with HIV.[4] Abrupt suspension of antiretroviral treatment increases the risk of rebound viremia.[5] Research has shown a link between treatment interruptions and not only opportunistic infections but also all-cause mortality (i.e. death from non-HIV related causes).[6] The Medicare Part D rule change proposal as written would likely lead to both of these outcomes, because treatment interruptions caused by formulary challenges and prior authorization delays would be inevitable.

Providing medical care to an HIV-infected patient is a complex endeavor. Providers titrate treatment based on a variety of factors. Forcing Medicare beneficiaries to adjust treatment regimens that they have developed with their providers, and increasing physician burden—solely based on cost concerns—could worsen treatment outcomes for PLWH in the U.S. Older adults' ability to metabolize antiretroviral medications is diminished, relatively to younger patients, and may result in increased toxicity.[7] Long exposure to highly active antiretroviral therapy (HAART) may increase the risk of heart attack[8] and heart disease resulting from specific classes of

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[2] HIV.gov (2017, May 27). *HIV care and treatment activities*. https://www.hiv.gov/federal-response/federal-activities-agencies/hiv-care-and-treatment-activities

[3] Cahill S, Brennan M, Candelario N, Seidel L, Guidry J, Karpiak S. (2010, November 12) Emerging client and service issues for older people living with HIV/AIDS. Services and Advocacy for GLBT Elders conference. New York.

[4] Capeau J. (2011) Premature Aging and Premature Age-Related Comorbidities in HIV-Infected Patients: Facts and Hypotheses. *Clin Infect Dis*, 53(11), 1127-1129.

[5] Harding R, Simms V, Krakauer E, et al. (2011, Feb 15) Quality HIV Care to the End of life. *Clin Infect Dis*, 52(4), 553-554; author reply 554.

[6] The Strategies for Management of Antiretroviral Therapy (SMART) Study Group. CD4+ count-guided interruption of antiretroviral treatment. *N Engl J Med*. 2006 Nov 30;355(22):2283-96.

[7] Gebo KA. (2006) HIV and aging: Implications for patient management. *Drugs Aging*, 23(11), 897-913.

[8] Bhavan K, Kampalath V, Overton ET. (2008) The aging of the HIV epidemic. *Curr HIV/AIDS Rep*, 5(3), 150-158.

antiretrovirals.[9] Given the incidence of non-AIDS related comorbidities among older HIV-infected patients, closely monitoring and adjusting medication regimens may be necessary to minimize toxicities and drug-drug interactions.[10] In male HIV patients over 50 years and among postmenopausal women, bone density monitoring and adjustment of the antiretroviral regimen may be required in order to minimize the risk of fragility fractures.

Many antiretroviral medications, particularly those in wide use a decade or more ago, can cause liver toxicity. For HIV-positive people co-infected with hepatitis, the interaction of some anti-retrovirals and cholesterol medications can cause liver toxicity.[11] Other side effects resulting from antiretroviral use include lipodystrophy, osteoporosis, pancreatitis, peripheral neuropathy, and buildup of lactic acid.[12] Health care providers treating HIV-positive patients with multiple comorbid conditions must already balance a number of concerns. Forcing them to change antiretroviral treatment regimens and to replace medications that are working is bad medicine and bad public health policy.

Older adults living with HIV may experience cognitive impairment starting at an earlier age relative to their HIV-negative peers.[13] This could be due to "chronic HIV-driven inflammation in an aging brain."[14] Different antiretroviral medications vary in their ability to penetrate the central nervous system (CNS) and reduce CNS HIV viral load.[15] Declines in cognitive ability can reduce adherence to antiretroviral medication.[16] Antiretroviral therapy may increase the risk of Alzheimer's disease,[17] depression, and other psychiatric side effects.[18] A number of studies have

[9] Deeks SG, Phillips AN. (2009) HIV infection, antiretroviral treatment, ageing, and non-AIDS related morbidity. *BMJ*, 338, 288-292.

[10] AIDSinfo. (2016) Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents, Considerations for Antiretroviral Use in Special Patient Populations, HIV and the Older Patient. Retrieved from: https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/277/hiv-and-the-older-patient

[11] Gebo KA. (2006) HIV and aging: Implications for patient management. *Drugs Aging*, 23(11), 897-913.

[12] Ibid.

[13] Webel, A. R., Longenecker, C. T., Gripshover, B., Hanson, J. E., Schmotzer, B. J., & Salata, R. A. (2014). Age, stress, and isolation in older adults living with HIV. *AIDS Care*, 25(5), 523-531.

[14] Portegies P. (2010) HIV/HAART and the brain—what's going on? *J Int AIDS Soc,* 13(Supp14):035.

[15] Letendre S, M.-B. J., Caparelli E. (2008). Validation of the CNS pentration-effectiveness rank for quantifying antiretroviral penetration into the central nervous system. *Arch Neurol, 65*, 65-70.

[16] Ettenhofer ML, H. C., Castellon SA, Durvasula R, Ullman J, Lam M, Myers H, Wright MJ, Foley J. (2009). Aging, Neurocognition, and Medication Adherence in HIV Infection. *American Journal of Geriatric Psychiatry, 17*(4), 281-290. doi: 10.1097/JGP.0b013e31819431bd

[17] Myers JD. (2009) Growing old with HIV: The AIDS epidemic and an aging population. *JAAPA*, ;22(1), 20-24. Cited in Cahill S., Valadez R. Growing older with HIV/AIDS: New public health challenges. *Am J Public Health.* 2013 Mar;103(3):e7-e15. doi: 10.2105/AJPH.2012.301161. Epub 2013 Jan 17.

[18] Simone M, Appelbaum J. (2008) HIV in older adults. *Geriatrics*, 63(12), 6-12. Cited in Cahill and Valadez, 2013.

found high rates of depression among older people living with HIV.[19,20,21] Depression can correlate with low rates of antiretroviral medication adherence. Treatment with antidepressant medication can improve antiretroviral adherence.[22] For these reasons, we are concerned with the proposal to remove protected class status for antidepressants and antipsychotics.

Miraculously, thousands of PLWH who a quarter century ago nearly died of AIDS are today thriving as older adults and long-term survivors living with HIV. This did not just happen. This was the result of closely monitored care partnerships between providers and patients, often with the help of critical support services such as case management and treatment adherence counseling. The proposed changes would throw a monkey wrench into the success we have achieved with HIV care over the past quarter century, and could worsen health outcomes for people living with HIV. Please do not move forward with this proposal.

Should you have any questions, please contact Carl Sciortino, Vice President of Government and Community Relations, at csciortino@fenwayhealth.org or at 857-313-6572. Thank you for considering this comment on this important issue.

Sincerely,

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[19] Heckman TG, Kochman A, Sikkema KJ, Kalichman SC. (1999) Depressive symptomatology, daily stressors, and ways of coping among middle-age and older adults living with HIV disease. *J Ment Health Aging,* 5, 311-322. Cited in Schrimshaw EW, Siegel K. (2003) Perceived barriers to social support from family and friends among older adults with HIV/AIDS. *J Health Psychol*, 8(6), 738-752.

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[22] Moore DJ, Posada C (2013, January). HIV and psychiatric comorbidities: What do we know and what can we do? *Psychology and AIDS Exchange Newsletter*. American Psychological Association.

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