



May 16, 2018

The Honorable Kent Sullivan
Insurance Commissioner of Texas
Texas Department of Insurance
PO Box 149104
Austin, Texas 78714-9104

Re: Impact of Prohibiting HIV Prescription Drug Co-pay Cards from Counting Towards Deductibles and Maximum Out-of-Pocket Expenses

Dear Commissioner Sullivan:

We the 60 undersigned organizations of the HIV Health Care Access Working Group (HHCAGW), a coalition of national and community-based HIV service organizations, are requesting that you undertake an investigation of **a new practice that many insurance plans, employers, and pharmacy benefit managers are instituting that limits access to HIV and hepatitis C medications. Some plans are preventing manufacturer co-pay assistance contributions from counting towards a beneficiary's deductible and maximum out-of-pocket spending limits.** Plans are implementing these policies with no consumer notice, leaving consumers to find out that this policy is in place after they incur steep prescription drug cost sharing mid-year. These policies are unfair to the consumer and will have significant individual and public health consequences.

Importance of Access to HIV Medications

While we recognize drug prices are increasing and need to be addressed, access to medications is critically important for people living with HIV, and now, for people who are at higher risk of HIV. If a person living with HIV has access to antiretroviral drugs and is adherent to their medication regimen, that individual can live a long, healthy life largely unaffected by this disease. Furthermore, if an individual living with HIV is on antiretroviral treatment, their HIV can be suppressed to such a level that the possibility of transmitting the virus is essentially non-existent. Therefore, HIV treatment is also effective HIV prevention.

Additionally, people who do not have the virus, but are at higher risk of contracting HIV, can take a medication to prevent infection. This medication regimen is known as pre-exposure prophylaxis (PrEP). PrEP is a Food and Drug Administration (FDA)-approved medication that when taken consistently, reduces the risk of HIV infection by between 92 and 99 percent.

Suitable generic alternatives are not currently available for HIV prevention and for the treatment of HIV and HCV. While some generic alternatives are available for HIV treatment regimen components recommended for most patients in the *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* maintained by the Department of Health and Human Services, these require breaking up single-tablet regimens widely considered important to adherence and still involve at least one brand-name drug with no generic equivalent.¹ Without the co-pay assistance, most people living with HIV will be unable to afford their treatment throughout the plan year, and individuals trying to protect themselves from HIV will be left at greater risk of acquiring the virus.

High Beneficiary Cost-Sharing Limits Access

Today, one of the greatest obstacles facing HIV-positive people, and those who would like to access PrEP, is the cost of medications. Even for people covered through the private and employer insurance market, the financial burden of increasingly high deductibles and high co-insurance reduces the affordability, and thus the adherence rates, to these drugs. This is particularly true given that the vast majority of medications used to treat HIV and the only drug currently approved for PrEP are not available in generic form and, when covered by insurance plans, are almost always placed on the highest cost-sharing tiers. While in the past, many plans had first dollar coverage for prescription medications, more plans today are requiring individuals and families to first meet a deductible that can be several thousand dollars, with co-insurance rates as high as 50 percent after the deductible is met. High deductibles, coupled with high cost-sharing, prohibit many people from being able to afford their critically necessary medications and treatments.

- According to the Kaiser Family Foundation (KFF) 2017 Employer Health Benefits Survey, the average deductible for people with employer-sponsored coverage was \$303 in 2006, rising to \$1505 in 2017².
- In the same report, KFF found that more employees are enrolled in high-deductible plans—up to 28% in 2017—as compared to five years ago when 19% of people were enrolled in a high-deductible plan offered by an employer.

¹ HHS Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. 2017 Oct 17. <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/37/>

² <https://www.kff.org/report-section/ehbs-2017-section-8-high-deductible-health-plans-with-savings-option/>

- For plans offered in the individual marketplace, Avalere’s analysis found that the national average for the popular silver-tier plan deductible increased from \$2,658 to \$3,937 between 2015 and 2018³.

Co-pay Cards Enable Beneficiaries to Access Drugs

To assist people living with HIV or people on PrEP in affording their prescriptions and adhering to them, pharmaceutical manufactures have offered co-pay assistance programs. This assistance reduces the amount the beneficiary pays for their medication and helps them meet their deductible and maximum out-of-pocket spending limit. The availability of this assistance has enabled people living with HIV to remain alive and healthy. Without the copay assistance programs beneficiaries would not be able to afford their medications, daily adherence would be endangered, and the public health jeopardized.

Financial Impact on Patients

The new practice preventing co-pay assistance contributions from counting towards a beneficiary’s deductible and maximum out of pocket spending limits leaves individuals at risk for discontinuing HIV treatment. By doing so, insurance companies are creating an environment that will lead to poorer health outcomes and increased rates of new infections, and higher costs for health plans. This practice is particularly concerning when applied to medications for which there is no generic alternative, which is the case for the vast majority of drugs used to treat and prevent HIV. In those cases, failing to count co-pay assistance cards toward a consumer’s deductible and out-of-pocket maximum leaves the consumer with no affordable coverage option.

The financial impact of the change is not felt until several months into the year, and beneficiaries have no idea how much this change will cost them until they pick up their prescriptions at the pharmacy. Unaware of the change, many consumers find themselves reaching a “cost cliff” mid-year. After hitting the maximum on their co-pay card assistance, they pick up their prescription only to discover that the co-pay card has not been counted toward the deductible and they now will owe over a thousand dollars per refill to continue their medication. This likely will cause dangerous treatment disruptions mid-year as medication becomes prohibitively expensive without warning.

Appended to this letter are four case studies illustrating the dramatic financial impact patients will experience when copay cards are not counted towards the deductible and out-of-pocket maximum as they access HIV medications for prevention and treatment and HCV curative medications.

In Case Study 1, a patient accessing PrEP for the prevention of HIV in a plan that utilizes co-pays but does not allow the co-pay assistance to count toward the deductible will face annual total out of pocket expenses of \$3,400 (\$1,676 in just one month) compared to zero costs if the

³ <http://avalere.com/expertise/managed-care/insights/silver-exchange-premiums-rise-34-on-average-in-2018>

assistance was allowed to count. If a 20 percent co-insurance was used for PrEP (Case Study 2), annual patient costs would increase from \$1,200 to \$5,461, a difference of \$4,261. Similarly, a patient utilizing a single-tablet regimen to manage their HIV, as shown in Case Study 3, would pay \$3,500 more per year (\$2,870 in one month). In Case Study 4, for a patient on treatment to cure their hepatitis C, they would need \$3,050 to begin their treatment versus just \$5 if the plan counted the co-pay assistance. As illustrated in each of the case studies, the insurance plans will be collecting thousands of dollars more for each drug by not allowing the co-pay assistance to count towards the deductible.

In addition to the financial upheaval related to dramatically increased patient cost-sharing, beneficiaries are shocked by the abrupt change in their insurance coverage. Insurance plans have not adequately notified their beneficiaries of this change, leading people to continue to engage in their health care and financial planning in the new year just as they have in the previous years, unaware that the circumstances have changed. An issuer's policy with regard to manufacturer co-pay cards has been difficult for patients to find and to understand. In some instances, plans are applying it to only certain classes of drugs and not others, which call into question the motives behind these decisions. In some cases, the policy appears to impact the entire prescription drug benefit, while in others it is limited only to drugs accessed through a specialty pharmacy. For the latter, consumers are not well informed of any option they may have to opt out of the specialty pharmacy and pick up their drugs at a retail brick-and-mortar pharmacy, where the co-pay accumulator policy does not apply. This lack of transparency and confusion over when and how the co-pay accumulator operates leaves consumers at risk for arbitrary and discriminatory insurance practices that target people living with particular conditions.

Given the high number of people living with HIV who are co-infected with hepatitis C virus (HCV), we are concerned that instituting this policy for curative HCV drugs will make access to these drugs out of reach to most people living with HCV. This will not only endanger their personal health but increase future medical costs and lead to future HCV infections

We strongly oppose these new policies and call on plans to reverse this practice. Given this damaging lack of transparency, plans should be required to post their co-pay card policies clearly in plan documents and formularies and notify their beneficiaries and health care providers explicitly and directly of changes to their policies. These disclosures should be in terms that are easy to understand and that demonstrate exact cost differences based on a beneficiary's medical history and previous explanations of benefits. Furthermore, plans should train call center employees to answer questions about the plans' co-pay card acceptance policy.

Some have stated that the existence of co-pay cards steer beneficiaries to particular brand name medications and away from generic medications. However, for the treatment of HIV and HCV as well as for PrEP, there are no acceptable generic treatments. The co-pay cards assist

beneficiaries in accessing their medications at a price they can afford for medications that are costly and life-saving.

We urge you to immediately undertake an investigation of these damaging practices.

Patients are already facing difficulties in affording their medications. This new practice will compound the situation.

Should you have any questions or need additional information about this issue, please feel free to contact Carl Schmid with The AIDS Institute at cschmid@theaidsinstitute.org, or HHCAGW co-chairs Robert Greenwald with the Treatment Access Expansion Project at rgreenwa@law.harvard.edu, Amy Killelea with the National Alliance of State and Territorial AIDS Directors at akillelea@NASTAD.org, or Andrea Weddle with the HIV Medicine Association at aweddle@hivma.org.

Thank you very much.

Sincerely,

ADAP Advocacy Association | ADAP Educational Initiative | Advocates for Youth | AIDS Action Baltimore | AIDS Alabama | AIDS Alliance for Women, Infants, Children, Youth & Families | AIDS Foundation of Chicago | AIDS Healthcare Foundation | The AIDS Institute | AIDS Project Rhode Island | AIDS Research Consortium of Atlanta | AIDS Resource Center of Wisconsin | AIDS United | American Academy of HIV Medicine | APLA Health | Bailey House, Inc. | Bronx Lebanon Family Medicine | Cascade AIDS Project | Center for HIV Law and Policy | Clare Housing | Coalition on Positive Health Empowerment | Communities Advocating Emergency AIDS Relief (CAEAR) | Community Access National Network (CANN) | Empower U Community Health Center | Fair Pricing Coalition | Georgia AIDS Coalition | Georgia Equality | Harm Reduction Coalition | HealthHIV | HIV Dental Alliance | HIV Medicine Association | Housing Works | Howard Brown Health | Human Rights Campaign | Hyacinth AIDS Foundation | Legal Council for Health Justice | Los Angeles LGBT Center | Michigan Positive Action Coalition | Minnesota AIDS Project | Nashville Cares | National Alliance of State and Territorial AIDS Directors | National Association of County and City Health Officials | National Black Gay Men's Advocacy Coalition | National Coalition for LGBT Health | National Latino AIDS Action Network | National Working Positive Coalition | NC AIDS Action Network | NMAC | Positive Women's Network - USA | Prism Health | Project Inform | Rocky Mountain CARES | San Francisco AIDS Foundation | SisterLove | Southern AIDS Coalition | Southern HIV/AIDS Strategy Initiative | South Florida AIDS Network - SFAN Broward | The Health Initiative | Thrive Alabama | Treatment Access Expansion Project | Treatment Action Group

APPENDIX – CASE STUDIES

CASE STUDY 1: PrEP – Silver Level High Deductible Plan (Co-Pay)

Plan annual OOP maximum: \$6,000
 Deductible (combined medical and Rx): \$3,000
 Drug cost sharing for preferred brand: \$50 after deductible
 Industry co-pay assistance program (CAP) annual maximum: \$4,800
 WAC monthly drug price: \$1,676

	Medication Costs <i>Counting Industry Co-pay Card Toward Deductible and OOP Max.</i>		Medication Costs <i>Not Counting Industry Co-pay Card Toward Deductible and OOP Max.</i>	
	Consumer Pays	Industry Co-pay Card Pays	Consumer Pays	Industry Co-pay Card Pays
January	\$0	\$1,676	\$0	\$1,676
February	\$0	\$1,374	\$0	\$1,676
	Plan deductible hit			
March	\$0	\$50	\$228	\$1,448
			Industry CAP max. hit	
April	\$0	\$50	\$1,676	\$0
May	\$0	\$50	\$1,146	\$0
			Plan deductible hit	
June	\$0	\$50	\$50	\$0
July	\$0	\$50	\$50	\$0
August	\$0	\$50	\$50	\$0
September	\$0	\$50	\$50	\$0
October	\$0	\$50	\$50	\$0
November	\$0	\$50	\$50	\$0
December	\$0	\$50	\$50	\$0
Annual Consumer Cost	\$0		\$3,400	
Total Amount Collected by Insurance Plan	\$3,500		\$8,200	

CASE STUDY 2: PrEP – Silver Level High Deductible Plan (Co-insurance)

Plan annual OOP maximum: \$6,000
 Deductible (combined medical and Rx): \$3,000
 Drug cost sharing for preferred brand: 20% after deductible
 Industry co-pay assistance program (CAP) annual maximum: \$4,800
 WAC monthly drug price: \$1,676

	Medication Costs <i>Counting Industry Co-pay Card Toward Deductible and OOP Max.</i>		Medication Costs <i>Not Counting Industry Co-pay Card Toward Deductible and OOP Max.</i>	
	Consumer Pays	Industry Co-pay Card Pays	Consumer Pays	Industry Co-pay Card Pays
January	\$0	\$1,676	\$0	\$1,676
February	\$0	\$1,394	\$0	\$1,676
	Plan deductible hit			
March	\$0	\$335	\$228	\$1,448
			Industry CAP max. hit	
April	\$0	\$335	\$1,676	\$0
May	\$0	\$335	\$1,212	\$0
			Plan deductible hit	
June	\$0	\$335	\$335	\$0
July	\$0	\$335	\$335	\$0
August	\$280	\$55	\$335	\$0
	Industry CAP max. hit			
September	\$335	\$0	\$335	\$0
October	\$335	\$0	\$335	\$0
November	\$250	\$0	\$335	\$0
December	\$0	\$0	\$335	\$0
	Plan annual OOP max. hit			
Annual Consumer Cost	\$1,200		\$5,461	
Total Amount Collected by Insurance Plan	\$6,000		\$10,261	

CASE STUDY 3: HIV STR – Silver Level High Deductible Plan

Plan annual OOP maximum: \$6,000
 Deductible (combined medical and Rx): \$3,000
 Drug cost sharing for preferred brand: \$50 after deductible
 Industry co-pay assistance program (CAP) annual maximum: \$6,000
 WAC monthly drug price: \$3,090

	Medication Costs <i>Counting Industry Co-pay Card Toward Deductible and OOP Max.</i>		Medication Costs <i>Not Counting Industry Co-pay Card Toward Deductible and OOP Max.</i>	
	Consumer Pays	Industry Co-pay Card Pays	Consumer Pays	Industry Co-pay Card Pays
January	\$0 <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-top: 5px;"><i>Plan deductible hit</i></div>	\$3,050	\$0	\$3,090
February	\$0	\$50	\$180 <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-top: 5px;"><i>Industry CAP max. hit</i></div>	\$2,910
March	\$0	\$50	\$2,870 <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-top: 5px;"><i>Plan deductible hit</i></div>	\$0
April	\$0	\$50	\$50	\$0
May	\$0	\$50	\$50	\$0
June	\$0	\$50	\$50	\$0
July	\$0	\$50	\$50	\$0
August	\$0	\$50	\$50	\$0
September	\$0	\$50	\$50	\$0
October	\$0	\$50	\$50	\$0
November	\$0	\$50	\$50	\$0
December	\$0	\$50	\$50	\$0
Annual Consumer Cost	\$0		\$3,500	
Total Amount Collected by Insurance Plan	\$3,600		\$9,500	

CASE STUDY 4: HCV DAA – Silver Level High Deductible Plan

Plan annual OOP maximum: \$6,000

Deductible (combined medical and Rx): \$3,000

Drug cost sharing for preferred brand: \$50 after deductible

Industry co-pay assistance program (CAP) maximum: 25% of the catalog price for the product after \$5 paid by consumer

WAC monthly drug price: \$27,773

	Medication Costs <i>Counting Industry Co-pay Card Toward Deductible and OOP Max.</i>		Medication Costs <i>Not Counting Industry Co-pay Card Toward Deductible and OOP Max.</i>	
	Consumer Pays	Industry Co-pay Card Pays	Consumer Pays	Industry Co-pay Card Pays
January	\$5 <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 0 auto;">Plan deductible hit</div>	\$3,045	\$3,050 <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 0 auto;">Industry CAP max. hit; plan deductible hit</div>	\$6,943
February	\$5	\$45	\$5	\$45
March	\$5 <i>(12 wk. course of treatment complete)</i>	\$45	\$5 <i>(12 wk. course of treatment complete)</i>	\$45
April				
May				
June				
July				
August				
September				
October				
November				
December				
Consumer Cost to Cure	\$15		\$3,060	
Total Collected by Insurance Plan	\$3,150		\$10,093	