HIV Modernization committee recommendation:

Topic: Modernization and removing barriers to care related to cost, CoPay Accumulator

Health care costs continue to be a significant source of barriers to care for all patients. Individuals living with HIV are not exempt from this barrier, and in fact may have significant more challenges than an HIV negative person.

Strategies such as Treatment As Prevention (TaSP) and Undetectable equals untransmittable (U=U) are scientifically validated approaches to ending the HIV epidemic. When People living with HIV (PLWH) face barriers to medications such as costs, these strategies are jeopardized as is the overall health of the PLWH. Accelerated aging in the PLWH is a medical concern of growing significance, and access to medications is an important strategy to minimize long term effects of HIV. According to the CDC over 50% of the PLWH are now over the age of 50, making the HIV and aging a growing medical condition, as more PLWH are living healthier longer lives.

The Kaiser Family Foundation reported that annual deductible have increased over 25% during the past five years (American Society of Clinical Oncology, 2021). The American Society of Clinical Oncology in their position statement on copay accumulators highlight the rising costs of deductibles from 4% to 12% in the past 15 years (American Society of Clinical Oncology, 2021). These rising costs, along with other costs of living increases are a barrier to care for PLWH.

To help offset the costs of medications, manufactures have copay assistance programs and medication assistance programs. The goal of these programs is to help reduce the barriers of cost. All manufactures for HIV medications have programs to this affect.

Limitations on care or denial of care is a common practice among insurance companies and is hidden behind the mask of utilization management. The utilization policies do not positively impact the PLWH, they only benefit the insurance company. Copay accumulators are an example of a utilization management policy that only benefits the insurance company by allowing them to legally double dip on copay amounts that PLWH are subject to. Copay accumulator adjustment programs prevent funds provided by manufacture coupons from being applied to toward a patient's annual out-of-pocket maximum or deductible. Utilization management policies prevent the amount of the manufacture support from being applied to the patients out-of-pocket responsibility.

These copay accumulator policies undo the intended goal of manufacture assistance programs and remove an important safety net feature in our medical system. According to their position statement, the American Society of Clinical Oncology found that "these programs have the potential to harm patients by discouraging the appropriate utilization of specialty therapies and reducing adherence to recommended treatments" (American Society of Clinical Oncology, 2021). They go on to say that these programs contribute to lower monthly prescription fills, higher risk and rates of discontinuation, and lower proportion of days of coverage for medications (American Society of Clinical Oncology, 2021). All of these things have negative consequences on the work towards Ending the HIV Epidemic in the US.

AIMED ALLIANCE penned a letter to the Department of Health and Human Services related to the protections the section 1557 of the Patient Protection and Affordable Care with respect to possible

"discrimination on the basis of race, color, national origin, age, disability or sex (including pregnancy, sexual orientation, gender identity, and sex characteristics) in covered programs and activities. Our letter to HHS supported recognizing that Section 1557 includes discrimination in benefit design and excessive benefit utilization policies; and reiterated our long-standing position against the use of discriminatory quality adjusted life year (QALY) value assessments" (placeholder).

The AIDS Institute (www.aidsinstitute.org) also highlights the broken system that allows insurance companies and pharmacy benefit managers to essentially double charge patients for copayments, deductibles and medication expenses through these copay accumulator type programs. As a result of advocacy within the state of Florida by agencies such as the AIDS Institute, SB1480 and HB1063 have been introduced as possible legislation to protect Floridians from this predatory and over utilization process that is specifically prohibited in Section 1557 of the ACA legislation.

Fifteen states have either implemented legislation, or have pending legislation, around copay accumulator programs.

1. Arizona HB 166 HB166
2. Alabama HB 569 HB569
3. Connecticut SB003 SB003
4. Georgia HB946
5. Illinois HB0465 HB0465
6. Kentucky SB45 SB45
7. Louisiana SB94 SB94
8. Maine SB1783
9. North Carolina SB257
10. Oklahoma HB2678 HB2678
11. Tennessee HB2515 HB2515
12. Virginia HB2515 HB2515
13. West Virginia HB2770 HB2770
14. Delaware SB267 SB267 (introduced 4/14/2022)
15. Washington SB5610 SB5610 (effective 1/1/2023)

AIDS Institute has published the following examples of how copay accumulator negatively impact patients and positively impact insurance companies and pharmacy benefit managers.

How Copay Assistance Works with Copay Accumulator Adjustment Policies

When a patient who uses copay assistance has a health insurance plan with a copay accumulator adjustment policy, they may be confused when they have to pay the full cost of their medicines or their full deductible at the pharmacy counter several months into the plan year. At that point, they have spent their copay assistance and may have to pay their entire deductible (again) before they can get their prescription. Their pharmacy bill could run as high as several thousand dollars. Many patients cannot afford that and walk away empty-handed.

Copay accumulator adjustment policies put patients with chronic conditions in a tough position – forcing them to choose between their health and other financial obligations.

Example 1 is a simplified overview of how copay accumulator adjustment policies work for patients who use copay assistance.

Example 1

- Patient has a $1,000 deductible and $500 in copay assistance.

Without a Copay Accumulator Adjustment Policy

The $500 copay assistance *will* count toward the patient's deductible.

$1,000 - $500 = $500. The patient has to pay only the remaining $500 to reach their deductible.

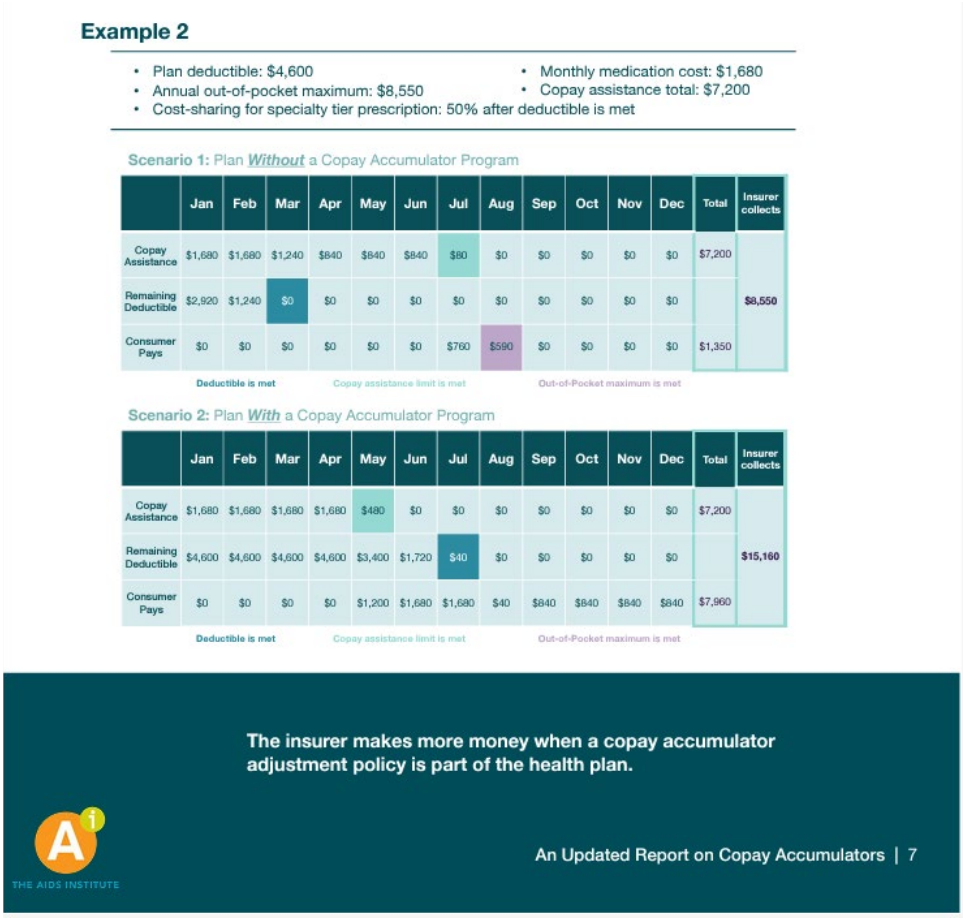
With a Copay Accumulator Adjustment Policy

The $500 copay assistance *will not* count toward the patient's deductible.

$1,000 - $0 = $1,000. The patient has to pay the full $1,000 to reach their deductible.

Example 2 below provides more detail on how, several months into the plan year, a patient's deductible has not been reduced by the amount covered by their copay assistance. In Example 2, when the patient goes to the pharmacy in May, their copay assistance would be maxed out, and they would have to pay for the remainder of the drug's cost. The patient would continue

(The AIDS Institute, 2020)



Example 2

- Plan deductible: $4,600
- Annual out-of-pocket maximum: $8,550
- Cost-sharing for specialty tier prescription: 50% after deductible is met
- Monthly medication cost: $1,680
- Copay assistance total: $7,200

Scenario 1: Plan *Without* a Copay Accumulator Program

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	Insurer collects
Copay Assistance	$1,680	$1,680	$1,240	$840	$840	$840	$80	$0	$0	$0	$0	$0	$7,200	
Remaining Deductible	$2,920	$1,240	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0		$8,550
Consumer Pays	$0	$0	$0	$0	$0	$0	$760	$590	$0	$0	$0	$0	$1,350	

Deductible is met — Copay assistance limit is met — Out-of-Pocket maximum is met

Scenario 2: Plan *With* a Copay Accumulator Program

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	Insurer collects
Copay Assistance	$1,680	$1,680	$1,680	$1,680	$480	$0	$0	$0	$0	$0	$0	$0	$7,200	
Remaining Deductible	$4,600	$4,600	$4,600	$4,600	$3,400	$1,720	$40	$0	$0	$0	$0	$0		$15,160
Consumer Pays	$0	$0	$0	$0	$1,200	$1,680	$1,680	$40	$840	$840	$840	$840	$7,960	

Deductible is met — Copay assistance limit is met — Out-of-Pocket maximum is met

(The AIDS Institute, 2020)

The examples can be viewed in their entirety at AIDS Institute Copay accumulator examples

Example 2 is a clear representation of the overcharging for services that patients experience by this discriminatory practice, that only serves to disenfranchise people from accessing needed medications.

This committee is recommending that legislation be drafted to be implemented into the 2023 legislative session to address and remove this barrier to care. This barrier negatively impacts PLWH, but on a broader scale, impacts every Nevadan that could benefit from manufacture assistance in reducing costs of medication.

Our recommendation is that this legislation be simple. Arizona drafted HB 2166 that makes clear the intent of the law and the problem it is designed to address.

AMENDING TITLE 20, CHAPTER 5, ARTICLE 1, ARIZONA REVISED STATUTES, BY ADDING SECTION 20-1126; RELATING TO INSURANCE COST SHARING.

Be it enacted by the Legislature of the State of Arizona:

Section 1. Title 20, chapter 5, article 1, Arizona Revised Statutes, is amended by adding section 20-1126, to read:

20-1126. Health care insurers; pharmacy benefits managers; cost sharing; calculation; definitions

A. WHEN CALCULATING AN ENROLLEE'S CONTRIBUTION TO ANY OUT-OF-POCKET MAXIMUM, DEDUCTIBLE, COPAYMENT, COINSURANCE OR OTHER APPLICABLE COST SHARING REQUIREMENT, THE HEALTH CARE INSURER THAT PROVIDES PHARMACY BENEFITS OR A PHARMACY BENEFITS MANAGER THAT ADMINISTERS PHARMACY BENEFITS FOR A HEALTH CARE INSURER SHALL INCLUDE ANY COST SHARING AMOUNT PAID BY EITHER THE ENROLLEE OR ANOTHER PERSON {OR ENTITY} ON BEHALF OF THE ENROLLEE FOR A PRESCRIPTION DRUG THAT IS EITHER:

1. WITHOUT A GENERIC EQUIVALENT.

2. WITH A GENERIC EQUIVALENT WHERE THE ENROLLEE HAS OBTAINED ACCESS TO THE PRESCRIPTION DRUG THROUGH ANY OF THE FOLLOWING:

(a) PRIOR AUTHORIZATION.

(b) A STEP THERAPY PROTOCOL.

(c) THE HEALTH CARE INSURER'S EXCEPTIONS AND APPEALS PROCESS.

B. FOR THE PURPOSES OF THIS SECTION:

1. "GENERIC EQUIVALENT":

(a) MEANS A DRUG THAT HAS AN IDENTICAL AMOUNT OF THE SAME ACTIVE CHEMICAL INGREDIENTS IN THE SAME DOSAGE FORM, THAT MEETS APPLICABLE STANDARDS OF STRENGTH, QUALITY AND PURITY ACCORDING TO THE UNITED STATES PHARMACOPEIA OR OTHER NATIONALLY RECOGNIZED COMPENDIUM AND THAT, IF ADMINISTERED IN THE SAME AMOUNTS, WILL PROVIDE COMPARABLE THERAPEUTIC EFFECTS.

(b) DOES NOT INCLUDE A DRUG THAT IS LISTED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION AS HAVING UNRESOLVED BIOEQUIVALENCE CONCERNS ACCORDING TO THE ADMINISTRATION'S MOST RECENT PUBLICATION OF APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS.

2. "HEALTH CARE INSURER" HAS THE SAME MEANING PRESCRIBED IN SECTION 20-1379.

Sec. 2. Effective date

Section 20-1126, Arizona Revised Statutes, as added by this act, is effective from and after December 31, 2019.

Thank you for the opportunity to participate in this value committee that together we can modernize HIV in Nevada, and move Nevada toward a resolution of the HIV epidemic in our State.