ISSUE BRIEF

NASTAD

ALTERNATIVE FUNDING PROGRAMS (AFPs)

Challenges in Accessing Essential Medicines for People Living with HIV/AIDS

The emergence of alternative funding programs (AFPs) contracted by self-insured employer health plans reflects a growing trend to reduce expenditures on high-cost specialty drugs. While these programs aggressively promise substantial savings for employers, they understate the significant barriers and financial insecurity they impose on employees, especially those managing chronic conditions. This is especially true for people living with HIV/AIDS, many of whom rely on safety-net programs like the Ryan White HIV/AIDS Program (RWHAP) and state AIDS Drug Assistance Programs (ADAPs). By design, AFPs may disrupt access to antiretroviral (ARV) therapies and other essential medicines, effectively shifting the financial and logistical burdens from employers to their employees and introducing risks for patients and broader public health.

What are Alternative Funding Programs?

AFPs are typically administered by third-party vendors under contract with employer-sponsored health plans and sometimes market themselves as a patient advocacy group. AFPs are employed as a strategy to manage the cost of specialty drugs. According to a 2022 study by Gallagher Research & Insights, among the 97 large employers representing approximately 4.7 million covered employees and their families, 10% of the employers reported current use of an AFP. An additional 8% planned to adopt an AFP within two years, and 19% anticipated adoption within three to five years.

Here's how AFPs generally operate:

- **Exclusion of Specialty Drugs:**
  Employers exclude select specialty drugs – high-cost outpatient medications used to treat rare, complex, or chronic conditions such as HIV – from their prescription drug benefit. Exceptions for self-funded plans within the Affordable Care Act's (ACA) Essential Health Benefit (EHB) requirements are often used as a justification for the specialty drug exclusions.

- **Limited Coverage Options for Employees:**
  Once a drug is excluded, employees generally have two options available to them: (1) pay for the full cost of the medication out-of-pocket, or (2) seek support through the employer's contracted AFP. In some cases, the AFP is affiliated with the plan's existing pharmacy benefit manager (PBM).

- **Redirection to External Assistance:**
  Employees enrolled in an AFP are then enrolled in external medication assistance programs. In certain cases, AFPs may even refer individuals to international drug importation channels to obtain needed medications at a lower cost.

How Do AFPs Interact with Other Medication Assistance Programs?

AFPs are designed to maximize existing medication assistance programs, primarily manufacturer-sponsored patient assistance programs and copay assistance programs, to secure access to high-cost drugs excluded from self-insured employer health plans.

EMPLOYER SELF-INSURED HEALTH PLANS AND ESSENTIAL HEALTH BENEFITS (EHB)

A self-insured health plan is one in which the employer assumes the financial risk of providing health benefits, paying directly for employees' medical care instead of purchasing insurance. These plans are more common among large employers and are often administered by third-party administrators (TPAs), including commercial insurers, who manage claims and services although the employer retains financial responsibility.

Self-insured plans are regulated federally under ERISA and are generally exempt from state insurance laws. According to the Kaiser Family Foundation's 2024 Employer Health Benefits Survey, 63% of covered employees are enrolled in self-insured plans.

These plans are also exempt from the Affordable Care Act's (ACA) requirement to cover the ten Essential Health Benefits (EHBs). However, they cannot impose annual or lifetime dollar limits on any EHBs they do choose to cover, including prescription drugs. If a drug is classified as a non-EHB, the plan may apply separate cost-sharing rules, and any out-of-pocket spending on that drug will not count toward the plan's deductible or out-of-pocket maximum.

Patient and Copay Assistance Programs (PAPs and CAPs)

PAPs, often operated by pharmaceutical manufacturers or affiliated charities, provide free or discounted drugs to uninsured or underinsured individuals who meet income-based eligibility thresholds, typically defined as a percentage of the federal poverty level (FPL)[1]. These programs function as payers of last resort. CAPs, in contrast, help offset out-of-pocket costs for individuals with commercial insurance.

AFPs argue that employees in self-insured plans that exclude certain specialty drugs are effectively uninsured or underinsured and therefore are eligible for PAPs. To apply, employees are often required to submit sensitive personal information, including household income and health status, and may need to sign a limited power of attorney authorizing the AFP to complete and submit the application on their behalf.

If approved, the medication is dispensed by the PAP's designated pharmacy, typically via mail or courier delivery, and it may require annual or semi-annual recertification. In cases where the employee qualifies only for CAPs, the manufacturer may cover part or all of the medication's cost. However, these payments generally do not count toward the employee's plan deductible or out-of-pocket maximum.

Barriers to Access and Legal Challenges with PAPs and CAPs

Despite AFP efforts, enrollment in PAPs is not guaranteed. Applicants may be denied if their income exceeds eligibility thresholds or if the manufacturer rejects the argument that the employee is "uninsured."

[1]The FPL is a specific dollar amount that changes annually and is based on the number of people in the household and whether the household is in Alaska, Hawaii, or the continental U.S. PAPs typically set their income limits at a percentage point above the annual FPL (e.g., 400% of the FPL for 2025 for a family of two residing in Georgia is $84,600 [$21,150 X 4.00]).

This creates a catch-22; PAPs may deny assistance because the individual has insurance, while copay programs may be inapplicable because the drug isn't covered by the plan. Without regulatory oversight of AFPs, several pharmaceutical manufacturers have initiated legal action, alleging that AFP practices are fraudulent and deceptive. If PAP enrollment fails, employers may choose to cover the drug or continue to deny coverage, leaving employees to shoulder the full cost themselves.

Implications of PAPs and CAPs for People Living with HIV/AIDS

For ARV medications to treat HIV, if a PAP application is denied, the employee may be referred to a state ADAP, especially if they appear uninsured and meet financial eligibility requirements. While many ADAPs provide both medication and insurance support for eligible individuals with employer-sponsored coverage, this process can delay access to treatment and shift costs to federally funded state programs with already limited resources. Additionally, employees who do not meet ADAP's income requirements are potentially left without alternative options.

Foreign Pharmacy Purchasing

When PAP enrollment fails, some AFPs resort to importing drugs from foreign pharmacies that offer significantly lower prices. While international drug importation has been discussed as a strategy to improve affordability, it poses major legal and safety risks. Except for narrow exceptions, importing prescription drugs from foreign pharmacies violates federal law, as these products are not subject to FDA oversight.

Medications from unauthorized foreign sources may be counterfeit, contaminated, or substandard, posing serious health risks. Patients relying on these pharmacies have no guarantee of product safety, no access to regulatory protections, and limited legal recourse in the event of harm. Encouraging or requiring patients to use foreign pharmacies as a cost-saving measure is not only ethically fraught, but also exposes them to potentially dangerous medications and undermines public health safeguards.

IS IT LEGAL TO IMPORT PRESCRIPTION DRUGS INTO THE U.S.?

Generally, importing prescription drugs into the U.S. is restricted under federal law, but there are limited exceptions:

1. **Manufacturer Importation:** A drug manufactured in an U.S. Food and Drug Administration (FDA)-inspected foreign facility may be legally imported if it is intended for U.S. consumers and imported directly by the manufacturer.
2. **Reimportation:** A drug that is FDA-approved and originally manufactured in the U.S. may be exported and later reimported under specific conditions, such as during a documented national shortage.
3. **Personal Use Exception:** On a case-by-case basis, the FDA may permit individuals to import a limited supply of a prescription drug for personal use. This applies only if:
   - The drug is not approved or available in the U.S.,
   - It is intended to treat a serious condition, and
   - The importation does not pose an unreasonable safety risk.

Even under these exceptions, the practice is heavily regulated, and most personal or commercial drug importation, particularly from foreign pharmacies not authorized

How do AFPs Impact Those Living with HIV/AIDS?

AFPs can exacerbate health and workplace inequities for people living with HIV/AIDS by creating significant barriers to timely, consistent access to essential medicines. These challenges not only threaten individual health outcomes but also perpetuate broader systemic disparities, particularly among uninsured or underinsured populations. Specific concerns include:

- **Treatment Delays:** Some of the most serious risks associated with AFPs include the potential for delays in initiating ARV treatment and potentially having to disrupt access to previously covered ARV treatment. Individuals may face delays ranging from weeks to months as they navigate complex enrollment processes. Employees may first learn their drug is not covered, then must research alternatives, apply for manufacturer PAPs, and, if denied, seek help from the RWHAP or state ADAPs. Of serious concern, interruptions in ARV therapy increase the risk of drug resistance and serious health complications.

- **Administrative Burdens:** Securing ARV medications through an AFP often involves substantial administrative effort, including submitting medical and financial documentation, communicating with multiple stakeholders, and possibly granting a limited power of attorney. This complexity can be frustrating and discouraging, particularly for individuals already managing chronic health conditions, and may lead some to forgo treatment altogether.

- **Exacerbation of Stigma:** The requirement of having to work with representatives of an AFP and having to provide sensitive personal and financial information to multiple entities—employer-sponsored plan administrators, the AFP vendor, pharmaceutical assistance programs—heightens privacy concerns and the fear of one's HIV status being mishandled or revealed. This administrative burden is not just a logistical challenge; it is an emotional one that can reinforce feelings of shame and the need for secrecy, which are hallmarks of stigma. Furthermore, the very existence of a separate, convoluted system for accessing life-saving medication can perpetuate the idea that HIV is a condition that falls outside the bounds of standard healthcare, further stigmatizing those who live with it.

- **Fragmented Pharmacy Care:** If an AFP client is successfully enrolled in a PAP, the medication is typically dispensed via mail-order from a separate pharmacy. This fragmentation can disrupt coordinated pharmacy care, increasing the risk of drug-drug interactions due to lack of communication between the patient's usual pharmacy and the PAP-contracted provider.

- **Strain on Safety Net Programs:** Although AFPs aim to reduce employer costs and maintain affordable employee premiums, these strategies may shift financial responsibility to already limited federal and state safety net programs. Relying on ADAPs and RWHAP to cover costs originally borne by employer-sponsored insurance raises ethical, fiscal, and access concerns, particularly when those programs were designed to support the most vulnerable individuals.

THE HIDDEN COSTS OF COST-SHIFTING: HOW EMPLOYER USE OF SAFETY NET DRUG PROGRAMS UNDERMINES EQUITY AND ACCESS

The practice of shifting prescription drug costs from employer-sponsored insurance plans to safety net programs, such as manufacturer PAPs and ADAPs, raises several critical concerns:

1. Undermining the Purpose of Safety Net Programs:
These programs are designed to support low-income, uninsured, or underinsured individuals who lack access to affordable medications. When employers and AFPs use them as cost-containment tools, they divert limited resources away from the populations they were intended to serve.

2. Straining Finite Resources:
Manufacturer PAPs, charitable foundations, and publicly funded programs like ADAPs operate with limited budgets. Increased reliance by large employers increases demand, putting additional pressure on already overburdened systems and potentially limiting access for those most in need.

3. Raising Ethical Concerns:
Passing the cost of expensive medications onto external assistance programs allows employers to reduce their financial liability while still claiming to offer comprehensive benefits. This raises ethical questions about fairness, responsibility, and the integrity of employer-sponsored health coverage.

4. Creating Inequities in Access:
Not all employees will qualify for third-party assistance. If employer plans exclude key medications and depend on outside programs, some individuals may face gaps in coverage, especially if eligibility criteria are restrictive or funding is reduced.

5. Increasing Administrative Complexity:
Navigating multiple assistance programs adds complexity to the medication access process, requiring coordination between employers, third-party administrators, manufacturers, and charities. This can introduce delays, errors, and administrative burdens for both patients and healthcare providers.

6. Opening the Door to Systemic Misuse:
Incentivizing employers to minimize costs by outsourcing coverage to external assistance programs risks institutionalizing a cost-shifting model that evades the responsibilities of providing adequate health benefits. This ultimately compromises the stability and sustainability of safety net systems.

What Can RWHAP Providers and State ADAPs Do to Help Those Living with HIV/AIDS and Impacted by AFPs?

Helping people living with HIV/AIDS enrolled in employer-sponsored insurance plans that do not cover ARV medications or other high-cost prescriptions requires coordination, advocacy, and strategic use of available resources. Below are key strategies RWHAP providers and ADAP staff, including case managers, can use to support clients:

1. Explore Full Range of Employer-Sponsored Insurance Benefits

- **Review Plan Coverage:** Assist clients in reviewing their insurance to identify gaps and understand what medications and services are included.
- **Support Appeals:** Help clients file appeals or request medical exceptions, especially when treatment continuity is at risk.

2. Leverage RWHAP and ADAP Resources

- **Access to ARVs:** For clients whose insurance does not cover ARVs, facilitate access to ADAP to secure essential medications.
- **Insurance Premium Assistance:** Explore ADAP-funded insurance premium assistance for clients who may benefit from alternative coverage, such as a Marketplace plan.

3. Provide Education and Empowerment

- **Insurance Literacy:** Teach clients how to navigate insurance systems, including understanding formularies, prior authorizations, and mail-order pharmacy policies.
- **Self-Advocacy Skills:** Equip clients with tools to advocate for coverage, file exceptions, and communicate effectively with insurers.

4. Build Partnerships with Local HIV Support Networks

- **Collaborate with Community Organizations:** Partner with local HIV advocacy and support organizations to identify and devise strategies to help mitigate health care coverage challenges.
- **Engage in Policy Advocacy:** Participate in local or national advocacy efforts to ensure that employer-sponsored insurance plans improve their coverage of HIV-related medications.

5. Monitor Changes in Insurance Policy and Client's Eligibility

- **Ongoing Client Check-ins:** Stay updated on clients' employment, insurance status, and eligibility to proactively address new barriers.
- **Advocate for Systemic Change:** Advocate at a policy level for broader improvements in insurance coverage, ensuring that more employer-sponsored plans offer comprehensive HIV-related care.

By combining direct client support, insurance navigation, and systemic advocacy, RWHAP and ADAP providers can reduce disruptions in care, enhance treatment adherence, and improve long-term health outcomes for PLWH facing insurance coverage gaps.

CASE IN POINT: IOWA MEATPACKING INDUSTRY EMPLOYEES AND ARV ACCESS

Iowa's meatpacking industry is one of the largest providers of health insurance in the state. As of May 2020, Iowa had the highest concentration of meat processing jobs in the nation, employing over 26,000 people. Consequently, the industry is the primary payer for healthcare for many people living with HIV/AIDS in the state.

However, many of these employer-sponsored insurance plans utilize AFPs, creating significant barriers to accessing essential medications. Brittany Kuehl, Iowa's Ryan White Benefits Coordinator and ADAP administrator, reports that approximately 175 of the state ADAP's clients have employer-sponsored insurance. "Between 20 and 25 of these clients are employed by the meatpacking industry and have insurance that doesn't cover ARVs," Kuehl stated. "They've all had to navigate this serious deficit in their coverage".

This situation is compounded by the fact that many employees in this industry are non-English-speaking and have limited health literacy, making it difficult to navigate the complex healthcare system. "Fortunately, many HIV-positive employees of these companies are already RWHAP clients and know to bring coverage concerns to their case managers," Kuehl noted.

In these cases, the state's ADAP intervenes by enrolling employees into a full-pay medication program that purchases the necessary ARVs for them. While this ensures treatment access, Kuehl explained that the preferable solution would be to "provide them with individual commercial plan coverage that provides the comprehensive care and treatment they need". The primary obstacle is that employers may not release employees from their self-insured plans.

Iowa is one of several states where self-insured employer health plans deny coverage for essential HIV medicines. This practice forces employees to navigate AFPs and ultimately strains the resources of the Ryan White HIV/AIDS Program to ensure treatment continuity.

"These programs are shifting the burden of accessing lifesaving treatment onto programs like state ADAPs and vulnerable people," Kuehl concluded. "It's unnecessary and dangerous."

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