

Alternative Funding Programs

What Employers Need to Know



What Are Alternative Funding Programs?

The purpose of this white paper is to explain the unintended consequences of alternative funding programs, raise attention to the risks for employers and employees, and provide more ethical cost-containment strategies for employer-sponsored health plans.

A recent survey showed that the vast majority of employers think health benefit costs are excessive, with four in five believing these costs will become unsustainable in five to ten years.

[1] These concerns are warranted and reflect a decade-long rise.

Annual premiums per employee in 2023 cost employers an average:

\$7,034 for single coverage

+

\$17,393 for family coverage [2],[3]

Key Definitions

Alternative Funding Program (AFP):

Programs designed by for-profit third-party vendors and marketed to employer-sponsored self-funded health plans. AFP vendors either work with the health plan to exclude specialty drugs from coverage or deny prior authorization for specialty medications. In both instances, vendors then seek to procure the employee's medication from a manufacturer patient assistance program (PAP).

Patient Assistance Program (PAP):

Programs offered by drug manufacturers that directly supply prescription drugs at no cost to uninsured or underinsured patients.

Copay Assistance:

Financial aid offered by drug manufacturers and non-profit organizations to help patients afford the copay for their medication.

Specialty Drugs:

Prescription drugs treating rare, chronic, or complex conditions that may require special handling and close patient management; they are often higher priced than non-specialty drugs.



Alternative Funding Programs What Employers Need to Know

This trend is forecasted to continue with a 5.4%-8.5% increase in healthcare costs predicted for 2024 - potentially the largest jump since 2014.[4]

As a result, several cost-containment tools have been marketed to employers, one of the newest being alternative funding programs (AFPs). AFPs are designed by for-profit third-party vendors and marketed as a cost-saving tactic for self-funded employer plans. Some of these vendors operate by carving-out (i.e., excluding) specialty medications to make employees appear uninsured or underinsured and others operate by denying prior authorization for specialty medications. In both instances, vendors then seek to procure the employee's medication from a manufacturer patient assistance program (PAP), which supplies prescription drugs at no cost directly to consumers.

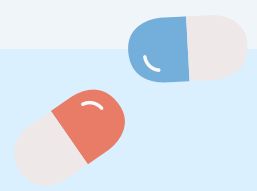
From 2021 to 2022, adoption
of AFPs skyrocketed from:

8% → 14%
of employers [5]

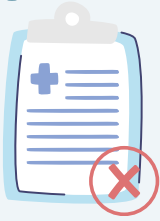


Employers should consider that while these programs are pitched as cost-saving solutions, in reality, they can interfere with their employees' ability to access the correct treatments in a timely fashion, potentially affecting their health and work performance and impacting employees emotionally, physically, and financially. [6] Meanwhile, employers bear the cost of AFP vendor fees, potentially higher employee health claims, and additional administrative time needed to implement these programs.[7]

How AFPs Work



1



Specialty Drugs Excluded from Coverage or Denied Prior Authorization

Alternative funding vendors work with self-funded employer health plans to either exclude specialty medications from coverage or to deny prior authorization for specialty medications. Some AFPs operate by claiming specialty medications are “non-essential health benefits” (non-EHBs).[8]-[12] Employees whose medication is excluded appear to lack coverage, but whether the drug is excluded or denied prior authorization, employees are directed to work with the vendor implementing the AFP to attempt to secure their medication through a manufacturer PAP.[13]

2



Employee Provides Personal Information to AFP Vendor

Because manufacturer PAPs were specifically created to provide free medication as a stop-gap for truly uninsured or underinsured patients who would otherwise lack access, there are patient eligibility requirements including coverage and income limitations, among others. As such, the employee who is affected by either type of AFP must provide the AFP with personal and financial information which the AFP uses to complete the employee’s PAP application.[14]

3



AFP Vendor May Pursue Other Avenues If PAP Fails

If the employee is ineligible for a manufacturer PAP or if there is no PAP available for the prescribed medication, the AFP may attempt to import the medication from abroad in potential violation of the Federal Food, Drug, and Cosmetic Act.[15],[16] On occasion, AFPs may also seek financial assistance from nonprofit organizations while awaiting determination of an employee’s PAP eligibility.

The Result...

If the medication is secured for free through the PAP or is imported from a foreign pharmacy, the employer’s short-term healthcare costs may be reduced, with the AFP vendor taking a cut of these savings (anywhere from 20%-30%) or charging a flat fee.[17],[18]

If alternative funding is not secured and the drug is not sourced from abroad, the prescription may boomerang back to the employer, who has the option of covering it as a normal pharmacy benefit – rendering the entire process ineffectual.[19] In some cases, the drug will not be covered at all.[20]

Distinguishing AFPs

Three important distinctions should be made:

- 1 AFPs vendors should not be classified as patient advocacy groups,** despite some claims to the contrary.[21] Patient advocacy groups are non-profit organizations that act on behalf of patients to support their needs and policy priorities. In contrast, AFP vendors are for-profit businesses that do not prioritize the best interests of patients. AFPs capitalize on assistance programs explicitly intended for truly uninsured and underinsured patients, while delaying treatment access to essential medications for enrolled employees. Any self-identification as a “patient advocacy group” is a misappropriation and could mislead vulnerable patient populations.
- 2 AFPs are not copay maximizers.** AFPs are frequently confused with another cost-containment tool called copay maximizers because, like copay maximizers, some AFPs allege specialty medications are non-EHBs. If a medication is not an essential health benefit, cost-sharing protections required under the Patient Protection and Affordable Care Act (ACA) do not apply, and employees may be held responsible for up to 100% of the cost of these medications if they do not abide by the terms of the AFP or copay maximizer.[22]-[24] Problematically, even if the employee chooses to pay for the medication themselves instead of joining the program, the non-EHB categorization used by some AFPs prevents the employee’s spending from counting towards their cost-sharing obligations, leading to higher out-of-pocket costs for other health expenses.[25],[26]

Although maximizers and AFPs have some similarities, there are several key differences. Whereas copay maximizers categorize specialty medications as “covered” non-EHBs, AFPs that operate by carving-out specialty drugs **exclude** coverage of these medications altogether. With copay maximizers, beneficiaries can still get their medication as a covered plan benefit, but their cost-sharing obligation is raised to “maximize” the amount of copay assistance that insurers and their affiliates can keep for themselves. A second key distinction between these programs is that AFPs primarily target manufacturer PAPs as well as foreign drug markets, whereas maximizers typically **only** seek out manufacturer copay assistance.[27],[28]

Distinguishing AFPs (continued)

- 3** There is a third cost-saving tactic known as copay accumulator programs which exploit manufacturer and nonprofit copay assistance. Copay assistance is third-party financial assistance provided to commercially insured individuals to help them meet their cost-sharing requirements (i.e., copays and coinsurance).

Unlike some AFPs and copay maximizer programs, copay accumulators do not rely on categorizing specialty medications as non-EHBs. Instead, a plan accepts the copay assistance that a manufacturer or nonprofit provides to a patient to help the patient meet their out-of-pocket expenses, but the plan does **not** count any of that assistance towards the beneficiary's deductible or out-of-pocket maximum.

In limited instances, AFPs may also attempt to get copay assistance from a nonprofit. This could occur as the AFP vendor awaits a patient's eligibility determination for a PAP; if the vendor is unable to source the drug from overseas; or when a denied PAP application leads an employer to cover the prescription as a pharmacy benefit, thereby making the patient once again "insured" for the drug and eligible for copay assistance. Overall, this process wastes precious time and results in treatment delays.

Ethical Issues and Impact on Employees

AFPs may cause emotional, financial, and physical harm to employees

Oncology Case Study:

The cancer community has confronted an unsettling case in which a large **health plan sponsor was fully aware that its AFP hindered access to life-saving chemotherapy drugs, yet persisted in using it under the conviction that costs were being saved.**[29] Postponing oncology treatments can be life-threatening, with a 4-week delay in systemic therapy increasing risk of death by up to 13%.[30] It is disheartening that any provider of health benefits would consciously prioritize saving money over protecting employee health.



Employers should be aware that AFPs harm employees on multiple fronts...

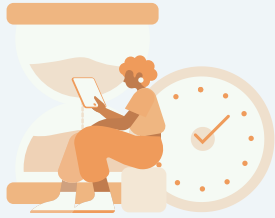


The design of these programs inherently coerces employees to enroll in the AFP, since their only other option is to pay for the full cost of the prescription drug. Because one's health status, condition, or disability can be very personal, employees may feel uncomfortable discussing the impact of these programs with their employer and may fear stigma or even termination if they disclose their condition.

Further, AFPs often collect highly sensitive and personal information from employees, such as salary, household size, and condition-specific details, in order to complete the PAP application.[31] Some AFPs even obtain a power of attorney from employees, permitting the AFP vendor to legally act on their behalf.[32] These are major privacy concessions for employees, who may not be fully informed how and why their data is being used.



Ethical Issues and Impact on Employees (continued)



The process of going through coverage denials and enrolling in the AFP is also an unnecessary barrier to accessing needed treatments. The delays caused by AFPs can be especially challenging for employees with an acute, life-threatening condition. Similarly, this process is frustrating for individuals with life-long chronic conditions who have already been through specialist referrals, dozens of tests, and failures on other medications. Even after completing the AFP process, the patient may be denied from the manufacturer PAP due to its eligibility requirements.

By singling out specialty medications, AFPs defy workplace equity and add obstacles for employees living with chronic diseases and disabilities. The lack of appropriate coverage could lead affected employees to prematurely leave the workforce and experience economic disadvantages as a result.[33]-[35] Before agreeing to an AFP, employers should keep in mind that supporting the wellbeing of all employees – regardless of their health or income – can improve a business' sustainability and growth.[36]



Lastly, employers should consider that AFPs have impacts beyond their own employees. AFPs steer individuals who would normally be covered by an employer-sponsored plan onto programs explicitly intended for those who are uninsured or underinsured. The exploitation of these limited safety nets jeopardizes their availability for patients who truly need them, threatening treatment adherence and health outcomes.[37],[38] In addition, the practice of sourcing drugs from abroad places patients at risk, depletes other nations' limited supplies, and could contribute to international shortages.[39] For employers with a global network of employees, this could shift healthcare affordability concerns from one market to another.



Legal and Regulatory Risks*

Employers should be mindful that AFPs raise a number of legal and regulatory concerns which, if challenged successfully, could expose them to liability.[40]



1. FDA *Food and Drug Administration*

Most flagrantly, AFPs that source drugs from abroad appear to act inconsistently with the U.S. Food and Drug Administration's (FDA) importation policies as stated in a warning letter to one AFP.[41]-[45] Because drugs from overseas may not be held to the same FDA safety standards, consumers risk receiving potentially inferior and unsafe products.



3. FTC *Federal Trade Commission*

AFPs may also be considered "unfair" trade practices under certain state and federal consumer protection laws because employees enrolled in an AFP may face unavoidable financial and physical harms: non-compliance with the AFP means higher cost-sharing responsibility, while compliance could delay receipt of treatment, resulting in negative health consequences.[47], [48] Finally, employers may shoulder long-term employee health costs on top of AFP vendor fees as a result of employees experiencing delays in accessing the appropriate treatments. [49]



2. HIPAA *Health Insurance Portability and Accountability Act*

By determining employee health benefits and ultimate treatment access based on a health factor (i.e., a chronic condition), the employer using an AFP is potentially transgressing the Health Insurance Portability and Accountability Act (HIPAA) non-discrimination requirements, which prohibit plans from using an individual's health status, condition, past care, or disability to discriminate with respect to their eligibility or benefits.[46]



4. ACA *Affordable Care Act*

Because prescription drugs are one of the ten essential health benefits under the Affordable Care Act (ACA), employer-sponsored health plans offering coverage for these are required to use a definition of prescription drugs that has been approved by the Department of Health and Human Services (HHS). Designating certain specialty drugs as non-EHBs is not an approved definition.[50]-[54]

*This content does not and is not intended to constitute legal advice.

Legal and Regulatory Risks* (continued)



5. ERISA & CAA


Employee Retirement Income Security Act & Consolidated Appropriations Act

Under the Employee Retirement Income Security Act of 1974 (ERISA) and the Consolidated Appropriations Act (CAA), employers are also responsible for acting solely in the interest of participants and beneficiaries for the exclusive purpose of providing benefits to them and prudently using health plan assets to provide comprehensive benefits.[55],[56] By prioritizing cost-savings over employee health, using plan assets to pay AFP administrative fees, and providing limited coverage, employers who adopt an AFP may be breaching their fiduciary duty, acting in the plan's cost-saving interest rather than the beneficiary's interest.

Challenges

Patient advocates, members of Congress, and Harvard's Center for Health Law and Policy Innovation (CHLPI) have already issued a number of letters to regulatory authorities raising many of these concerns.[57]-[62] The Coalition of State Rheumatology Organizations is also developing model legislation that states can implement in opposition to AFPs. Although state legislature would not directly apply to self-funded employer plans, its emergence could set a precedent and inspire change at the federal level, which would impact these plans.

Provider Story



Physicians have reported receiving letters from AFP vendors asking for a patient's prescription to be changed.[63] These requested switches were not due to clinical necessity but were a result of the AFP's failure to secure the originally prescribed medication. As manufacturers catch on to the exploitation of PAPs by AFPs, guardrails are being put in place to prevent AFP enrollees from being eligible for their PAP. These responses from manufacturers may make it increasingly difficult for employees to access their medication through an AFP, and may also create challenges for truly uninsured or underinsured patients when attempting to obtain their medication through the manufacturer PAP. Consequently, AFPs may harm not only the enrolled employees, but also those for whom PAPs are intended to help.

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Employer Risks

Lawsuits

Considering the many ways that AFPs may implicate statutory, ethical, and regulatory standards, the risks of AFP-related lawsuits are very real, and employers are not protected from potential legal culpability. Recently, a pharmaceutical company filed a lawsuit against an alternative funding program, alleging it fraudulently “maneuver[ed] ineligible patients into [the pharmaceutical company’s] PAP” and profited off funds intended to support uninsured and underinsured patients.[64] Although this particular lawsuit was against an AFP, employers should assess their own risk of liability. For example, AFPs could attempt to avoid culpability by claiming that they acted under the employer’s direction.[65]

Higher Long-term Medical/Drug Spending

Employers should also be aware that by delaying treatment access, AFPs can compromise employee’s treatment adherence, which has been shown to worsen health and increase disease progression.[66] As a result, employers could bear substantial costs stemming from absenteeism, presenteeism, and higher medical claims.[67]-[69] In fact, it is estimated that failing to support employee health could cost employers approximately \$530 billion per year and 1.4 billion lost workdays. [70]

Employee Turnover

Further, inadequate health benefits can prompt the loss of qualified, valued workers, generating considerable rehiring and training costs for employers.[71] Fifty-six percent of employees with employer-sponsored insurance cite satisfaction with their coverage as a key determinant of their retention.[72] The same survey found that top drivers of dissatisfaction were costs and inadequate coverage. Employers should understand that employees are not only considering their personal medical needs but those of their dependents as well. This is especially important for employees with genetic conditions, who may have several family members prescribed the same specialty medication.

What Employers Can Do

Employers are critical stakeholders in the future of AFPs



Transparency and Peer Education

As the ultimate decision makers in AFP adoption, employers are critical stakeholders and will determine the future of these programs. Because many employers are not aware of the risks of AFPs, this issue should be discussed with human resources, legal and compliance, and employer groups. If an employer still decides to implement an AFP after such considerations, the employer should only do so during open enrollment. In addition, the employer should be transparent with all employees about the upcoming AFP implementation and its real-life implications for employees and their dependents, including mandatory participation, drug sourcing, and procurement processes. Employers who have had a negative experience after adopting an AFP should educate their peers about the potential consequences.

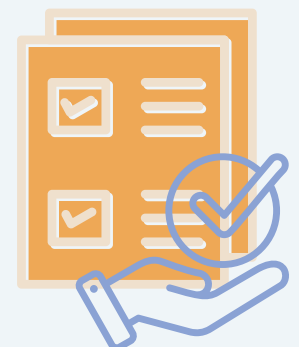
Informed Decision-Making and Conscientious Use of Benefits Consultants

It is also crucial that employers exercise prudence when soliciting guidance from health benefits consultants, as many consultants receive lofty referral fees from large pharmacy benefit managers (PBMs).[73] With the recent passage of the CAA, health benefits brokers and consultants must disclose compensation, increasing employer obligations to prudently accept their advice and recognize possible conflicting incentives.[74],[75] In doing so, employers can critically assess whether their health plan and adjunct programs like AFPs are truly in the best interest of their employees.



Anti-AFP Policies and Employee Protections

Finally, employers should include anti-AFP policies and specific protections in employment contracts. Establishing clear standards for equitable, comprehensive health benefits demonstrates a vested interest in employee wellbeing; this can have positive reputational impacts as patient-centricity is increasingly prioritized in healthcare.



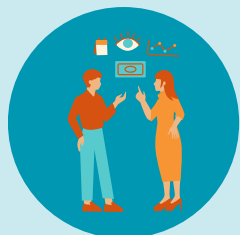
Alternative Strategies to AFPs

The costs of a self-funded health plan can be significant – but there are more effective and ethical ways to address increasing costs than resorting to AFPs



Choose the Right PBM

Instead of using an AFP to cut healthcare costs, self-insured employers should carefully assess their current benefits and **be selective when it comes to choosing a PBM**. With more than 60 PBM companies to choose from, employers should explore whether a different PBM may be a better fit for their coverage needs and leverage this competitive market to negotiate the best rates.[76] Smaller employers might consider a **multiple employer welfare arrangement (MEWA)**, in which multiple employers come together to enter into a larger health plan, increasing their bargaining power to negotiate better terms with insurance providers.[77]



Independently Manage Formularies

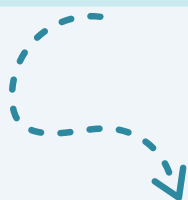
Another option for employers to consider is **independent formulary management**, in which the employer hand-picks drugs for coverage rather than opting for a PBM's pre-set formulary or consultant recommendations. By avoiding the complex web of PBM rebates and incentives, informed employers can achieve a better balance of cost-savings, fair cost-sharing, and sufficient coverage.[78]

↳ For example, five years after bypassing their PBM to initiate independent pharmacy contracts, a large construction and mining manufacturer had 13.8% lower per-member per-year costs and copay tiers were maintained over seven years.[79]



Offer Care Management Resources

Employers might also consider **offering employees access to a medical advocate program or patient navigators** to improve use of high-value care and to ensure employees with complex cases can efficiently access care. Patient navigators and medical advocate partners work with employees one-on-one to understand their benefits, overcome administrative obstacles, and ensure they are receiving sufficient, cost-effective care.[80],[81]



↳ One company rewarded employees who used patient navigators with lower cost-sharing; the employer ended up saving \$375,000 (37%) in two years while simultaneously eliminating or dramatically reducing employee cost-sharing.[82]

Alternative Strategies to AFPs (continued)



Invest in Preventative Healthcare and High Quality Primary Care

Investment in preventative healthcare and improved access to **high-quality, in-network primary care** can reduce medical and pharmacy spending while improving employee health. The provider network should also include **comprehensive care management centers**, which leverage an integrated, team-based approach to improve outcomes and lower costs.



For example, comprehensive care management in hemophilia is associated with a 40% lower chance of hospitalization and reduced mortality.[83] Similarly, higher patient retention in a comprehensive HIV infection clinic has been shown to reduce mortality.[84] Patients with diabetes have also experienced increased self-care behaviors, improved quality of life, and reduced use of emergency care thanks to their health center's comprehensive care design.[85]



Reduce Employee Cost-Sharing for Essential Medications

A number of studies have shown that **reducing employee cost-sharing for medications treating chronic conditions** can actually improve employee adherence and lower medical costs to the extent that the intervention is cost-neutral or in some cases cost-saving to the employer.[86]-[89]



A real-world analysis showed that a large employer experienced favorable medical spending trends after removing cost-sharing for primary care.[90]



In Summary: AFPs Are Harmful For Employers and Employees

As the critical intermediary between AFPs and patients, employers need to understand the reality of these programs:



AFPs shift the costs of specialty drugs off the employer-sponsored plan by exploiting alleged coverage loopholes for critical drugs and plundering free patient assistance intended for those truly without health coverage.



The arduous administrative process implemented by the AFP can substantially delay treatment access and damage employee health.

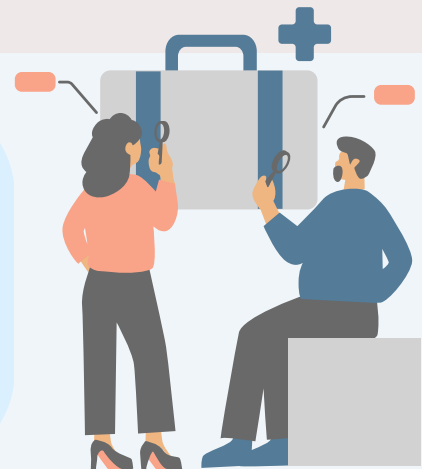


Vendor fees, long-term medical costs, and increased time to address compliance and legal considerations may outweigh an employer's realized savings from the AFP.



AFPs may result in employers facing liability for violating a number of legal and regulatory boundaries.

The coauthors of this white paper and represented patient communities urge employers to consider the risks associated with AFPs and the negative impact these programs have on their employees.



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