Alternative Funding Programs

Definition

An alternative funding program (AFP) is a third-party entity that works with employer-sponsored health plans to identify alternative ways to cover plan participants' high-cost specialty drugs. Plan beneficiaries under these programs are required to enroll in an AFP or otherwise cover 100 percent of the cost of their specialty medication that will not count toward their annual deductible or out of pocket maximum.

Background

The Affordable Care Act (ACA) created ten Essential Health Benefits (EHBs), all of which must be covered by ACA-compliant health plans. Prescription drugs are designated as EHBs and require coverage by a patient's health plan. Cost-sharing for the prescription contributes to the patient's annual limit on out-of-pocket cost. The ACA imposed annual limits on cost-sharing and capped patients' annual out-of-pocket spending on health care services. These regulations apply to all ACA-sponsored plans and employer-sponsored plans that voluntarily choose to cover EHBs. Employer-sponsored health plans that partner with AFPs preemptively determine that high-cost specialty prescriptions are non-essential and thus carve them out of coverage requirements. The designation of a prescription drug as a non-EHB also makes the patient responsible for 100 percent of the cost of the medication if they choose to pay out-of-pocket. If the patient chooses to work with an AFP the co-pay or the coinsurance will not count towards the patient's deductible or annual out-of-pocket limit.

How Alternative Funding Programs Work

Patients with rare and/or chronic conditions that require specialty medication are often subject to high cost-sharing to obtain these prescription drugs. Conditions requiring specialty medications can be life-threatening, including cancer, hepatitis C, or cystic fibrosis. In 2021, specialty drug expenditures in the United States were $301 billion. These specialty drugs make up a small portion of total drug utilization (2-3 percent), but a large proportion of total drug spending (51-60 percent).

Employers who may not want to cover these high-cost drugs can utilize AFPs to assist patients in finding alternative sources for coverage. Examples of alternative sources for specialty medication coverage include patient assistance programs (PAPs), international importation, co-pay assistance programs, or coupons directly from drug manufacturers. There are several types of PAPs, including manufacturer patient assistance programs that provide underinsured and uninsured patients with prescriptions free of cost, manufacturer copay assistance programs that pay for some or all of a patient's cost-sharing for a prescription, or charitable patient assistance programs that are operated by independent charitable foundations and provide financial assistance to those who meet their eligibility guidelines. PAPs are funded by pharmaceutical manufacturers, government agencies, or charitable organizations.

When using an AFP, an employer-sponsored plan categorizes specialty drugs as non-essential health benefits and therefore not subject to ACA coverage requirements. Then, a patient will be automatically denied coverage for this medication and is therefore labeled as "underinsured" which makes them eligible for a PAP. The AFP will reach out to the patient to confirm their information and if a patient qualifies, they will receive their specialty medication under the PAP. If they do not qualify, the AFP moves on to a different method of accessing the medication, for example international importation. If this option is also not available, a patient could choose to appeal the decision to their insurer or pay for their medication completely out of pocket, which could be very costly. Notably, a patient may not qualify for a PAP if their income is too high or if the PAP has been fully utilized and there is no more assistance available.

Compliance Risks and Ethical Concerns

The use of AFPs by employers or plans raises serious compliance concerns including ACA, Employee Retirement Income Security Act (ERISA), Food and Drug Administration (FDA), and Health Information Portability and Accountability (HIPAA) violations, as well as patient discrimination and violations of consumer protection laws. Under the ACA, prescription drugs are considered EHBs and by labeling certain drugs as non-essential, AFPs may be violating patient protections. By partnering with AFPs, employers may be breaching their fiduciary duty under ERISA and these partnerships could also violate HIPAA nondiscrimination requirements by singling out specific specialty medications or discriminating against a patient based on health status, medical condition, claims history, medical history, and/or disability. If an AFP imports prescription drugs from another country, it may be at risk of violating FDA regulations. An AFP may be seen as participating in unfair trade practices due to causing financial and/or physical harms to patients, which violates consumer protection laws, or even be exploiting PAPs which are intended for those who are truly uninsured or underinsured.

There are also ethical concerns with the AFP process. By pushing patients who have employer-sponsored health insurance into PAPs and misleadingly labeling them as “underinsured,” resources and grants are taken away from those who are truly uninsured and need charitable assistance. In addition to physical well-being, employers should consider the financial burden they could potentially place on employees who need specialty medications if it turns out they are ineligible for a PAP through the AFP.

Negative Impact on Patients

The application process and lengthy administrative back and forth between the patient and the AFP can be time consuming and result in delays accessing potentially lifesaving medication. In addition to delays, patients often must complete extra paperwork for the AFP to verify their eligibility for a PAP, which they could ultimately be found ineligible for due to having an income level that is too high. Additionally, a patient may be ineligible because a PAP is maxed out and there are no more available funds to disburse. Even if a patient is found eligible for PAP funding, they may not be able to continue with the same medication their physician has prescribed. Finally, if the only option available is international importation a patient may be vulnerable to potential dangers of imported drugs, which could range from being ineffective to being harmful to the patient’s health. Patients should utilize AFPs with caution and work with their physician and employer to ensure coverage for their prescription medications is uninterrupted.

In June 2023, a patient advocacy coalition met with the Department of Labor to share their concerns about the use of AFPs. Many of the concerns highlighted by the coalition are those discussed here.

Recent Legal Action

In 2023, Abbvie filed a lawsuit against Payer Matrix, LLC, an AFP, alleging that the company engaged in a “fraudulent scheme” that exploited Abbvie’s charitable PAPs intended for uninsured and underinsured patients in need. This case is ongoing.

Relevant AMA Policy

Policy D-110.983 states that the AMA will educate employers, benefits administrators, and patients on AFPs and their negative impacts on patient access to treatment and will advocate for legislative and regulatory policies that would address the negative impacts of AFPs.