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ALTERNATIVE FUNDING PROGRAMS: The Cost Saving Measure that Could Cost You

Typically, most prescription drugs require some form of cost-sharing from individuals with commercial insurance. For many individuals, cost-sharing obligations can be difficult to afford, especially for those who are prescribed more than one medication. A 2022 survey found that 6 in 10 respondents reported taking at least one prescription drug, and 25 percent reported taking four or more prescription drugs.[1] The same survey found that 20 percent of respondents taking one to three medications could not afford their health plans' cost-sharing requirements. This number increased to 32 percent for those who take four or more prescription drugs.[2] Some individuals who are unable to afford their medications may be forced to switch, ration, or abandon their treatments. Stopping treatments when not directed to do so by a health care professional can increase the risk of disease progression and hospitalizations.[3]

Consumers who cannot afford their cost-sharing obligations may be eligible for third-party financial assistance. Third-party assistance can come in many forms, including manufacturer copay assistance programs, charitable assistance programs, and financial assistance from friends and family.

Manufacturer copay assistance programs are for individuals with commercial insurance. A manufacturer copay assistance program can pay for some or all of an individual's cost-sharing for their medication. For example, if a health plan enrollee with a $100 copay participates in a manufacturer copay assistance program, the program could contribute $50 and the enrollee could pay the remaining $50.[4]

Charitable assistance programs can be used when an eligible individual is either underinsured or uninsured.[5] Eligibility requirements vary and can include diagnosis criteria, household income, family size, and medical expenses.[6] Some charitable assistance programs provide a medication directly to the consumer while others may provide some form of direct financial assistance.

Individuals enrolled in Medicare and Medicaid are not eligible for manufacturer copay assistance program because use of these programs violates the federal Anti-Kickback Statute.[7]

HEALTH PLANS WANT TO EXPLOIT FINANCIAL ASSISTANCE PROGRAMS

Typically, assistance from manufacturer and charitable programs will count towards the participating individual's cost-sharing obligations at the pharmacy counter, as well as their deductible and annual limit on cost-sharing. However, some health plans have adopted copay accumulator policies that accept third-party assistance on behalf of the consumer but do not count it toward the individual's annual limit on cost-sharing. As health plans have recognized that copay accumulator policies allow them to "double dip" by collecting revenue from both the assistance program and the consumer, more health plans have implemented these policies.

To further exploit this financial assistance, health plans have contracted with third-party specialty medication programs to help enroll health plan enrollees in financial assistance programs, irrespective of each enrollee's financial needs. One type of third-party specialty medication program is known as an alternative funding program.

WHAT IS AN ALTERNATIVE FUNDING PROGRAM?

When a health plan partners with an alternative funding program, the health plan defines all specialty medications as a non-essential health benefits (non-EHB).[8] By defining specialty medications as a non-EHB, health plans inform enrollees that they must either enroll with the alternative funding program or be responsible for 100 percent of the cost of the medication.[9] Because this medication is defined as a non-EHB, any cost paid for the medication by or on behalf of the enrollee will not count towards their deductible or annual limit on cost-sharing.[10] Given this coercive program design, plan enrollees are essentially required to enroll with the alternative funding program.

Once enrolled with the alternative funding program, the health plan automatically denies coverage for the enrollee's prescription medication.[11] The alternative funding program then steps in and obtains the enrollee's personal information such as household size and annual income to determine the type of third-party financial assistance the plan enrollee may be eligible for. Unlike typical non-EHB programs, which primarily enroll plan enrollees in manufacturer copay assistance programs, alternative funding programs determine whether enrollees are eligible for **manufacturer copay assistance programs, charitable assistance programs, and international importation programs.**[12]

If an individual is eligible for a manufacturer copay assistance program, the health plan will inflate the cost of the prescription drug to the maximum amount of manufacturer copay assistance available for the year. If the enrollee is eligible for a different program such as international importation, then enrollee will receive their medication through that source. However, if the enrollee is not eligible for any part of the alternative funding program, then the prescription will be sent back to the health plan for coverage and the medication will be covered like a regular pharmacy benefit.[13]

These programs are structured very similarly to non-EHB programs, which are sometimes referred to as "maximizer" programs. To learn more about these programs and how they define specialty medications as a non-EHB, read Aimed Alliance's non-EHB fact sheet.

CONSEQUENCES OF ALTERNATIVE FUNDING PROGRAMS

To ensure that individuals do not switch, ration, or abandon their medications due to cost alone, consumers have access to financial assistance programs. The financial value of this assistance is intended to benefit consumers not only by reducing costs at the pharmacy counter, but also by counting toward their annual limits on cost-sharing. However, when enrolled in an alternative funding program, the health plan accepts financial assistance on behalf of the enrollee but does not count the assistance toward meeting the enrollee's annual limit on cost-sharing. As a result, consumers are required to unnecessarily pay thousands of dollars more to meet their annual cost-sharing requirements. Further, copay assistance is not unlimited; it is subject to an annual cap. Once all available copay assistance is exhausted, it becomes increasingly difficult for enrollees to pay their copays, satisfy their deductibles, and reach their annual limits on cost-sharing. If a consumer is required to switch health plans mid-year but has exhausted all available copay assistance while enrolled under their previous plan, they will not be able to rely on copay assistance under the new plan the remainder of the year.

Moreover, when alternative funding programs force consumers who are able to afford their cost-sharing obligations to enroll in financial assistance programs, they jeopardize the availability of funds to support consumers who are actually *in financial need*. For example, charitable assistance programs are intended for individuals who are uninsured or underinsured, not for individuals who have adequate health insurance and are able to cover the cost of their medication but prefer not to do so. By exploiting such programs, alternative funding programs jeopardize the sustainability of important safety net programs intended for financially in-need consumers. As a result, charitable assistance programs could significantly decrease the number of consumers they can help. For some consumers, this may mean being forced to forego treatment due to unaffordability.

Lastly, alternative funding programs can mandate consumers import their medications from outside the United States. This could be problematic given that federal law prohibits the importation of drugs that have not been approved by the U.S. Food and Drug Administration (FDA), including "foreign versions" of FDA approved drugs.[14] Congress implemented this prohibition to help ensure that the domestic drug supply is safe and effective for consumers.[15] Regardless of whether a new drug is manufactured in the United States or in a foreign country, the drug must comply with federal law prior to being marketed in the United States. For example, it must be approved by the FDA, produced in FDA-inspected plants operating in accordance with current good manufacturing practices, and labeled with all required information.[16] As such, any entity that imports prescription drugs for human use into the United States must ensure that the drug satisfies these requirements.[17]

While importing unapproved prescription drugs is illegal, FDA's policy on importing prescription drugs for personal use recognizes that there may be circumstances in which the FDA may exercise enforcement discretion with respect to illegal importation.[18] The personal use policy, set forth in FDA's Regulatory Procedures Manual and endorsed under the FDCA, provides that *an individual* may be permitted to import an unapproved prescription drug for personal use if:

- The product is not used to treat a serious condition, such as the use of an over-the-counter treatment (OTC); or the product is used to treat a serious condition; and
- The product is needed to treat the serious condition and the medication is not available in the United States;
- There is no commercialization or promotion of the drug to U.S. residents;
- The drug does not represent an unreasonable risk;
- The individual importing the drug affirms in writing that the product is for personal use;
- The quantity is not more than a 3-month supply; and either: (1) the consumer provides contact information for the U.S. doctor providing treatment with the drug; or (2) the consumer provides evidence that the product is for continuation of a treatment begun in a foreign country.

However, the types of personal importation that the FDA anticipated when it developed this policy is far from what occurs with alternative funding programs. The FDA intended this policy to apply to importation by individuals, not large health plans attempting to lower their prescription drug costs. Thus, importation of prescription drugs by alternative funding programs likely falls outside of what FDA considers permissible conduct. If this practice is illegal, it raises questions about consumers' potential legal risks with respect to enrolling and participating in these programs.

WHAT CAN BE DONE TO HELP PROTECT PATIENTS?

Contact your elected officials and tell them to take action to protect consumers from alternative funding programs. State and federal legislatures need to be aware of these programs. Your story can play an important role in educating policymakers and lawmakers about why they must take action to prevent implementation of these programs. If you would like to share how you have been impacted by an alternative funding program, please email Aimed Alliance at policy@aimedalliance.org.

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