COPAY ASSISTANCE PROGRAMS AND COMPLIANCE RISKS – NO FREE LUNCH

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Self-insured plans looking for creative ways to minimize prescription drug costs are turning to vendors offering programs that attempt to utilize funds from drug manufacturers and other sources to subsidize these costs. Some of these programs involve leveraging the availability of drug manufacturer coupons or assistance and/or assistance from third parties (sometimes charitable) to pay for expensive prescription drugs. The catch: this assistance is available to the individuals who have been prescribed these drugs and not to the plans themselves.

Program sponsors attempt to overcome this hurdle by giving participants the option to either enroll in programs that use manufacturer assistance/alternate funding or not enroll in these programs and face either higher copays or the full cost for certain

drugs. Programs like copay maximizers and alternate funding programs are designed to take advantage of otherwise available financial assistance, but they raise potential compliance risks associated with these designs.

Some of these designs clash with Affordable Care Act ("ACA") rules on the annual maximum out-of-pocket limits ("the MOOP") for essential health benefits (EHBs) and/or raise red flags under the tax code and the Employee Retirement Income Security Act ("ERISA"). Self-insured plans need to be mindful of these compliance pitfalls and be aware of how proposed regulatory changes can adversely impact the touted benefits of these programs.

In our prior article, we detailed compliance issues regarding copay accumulators. Copay accumulators are programs that exclude the value of the manufacturer's assistance from accumulating toward the plan's ACA MOOP. Regulations that allowed this practice were vacated by a United States district court for the District of Columbia. An appeal from this decision was originally filed, but the government withdrew this appeal, indicating that the United States Department of Health and Human Services (HHS) would propose new regulations.

In the interim, HHS has stated, informally, that it will not take enforcement action against plans that do not apply coupons or other manufacturers' assistance toward the ACA MOOP. Our prior article also detailed the compliance issues that counting the assistance might raise for high deductible health plans (HDHPs) as to an individual's eligibility for a Health Savings Account.

In this month's article, we will focus on two related programs dealing with manufacturers and other prescription drug assistance: copay maximizer programs and alternative funding programs.

- **Copay Maximizer Programs:** Under a copay maximizer program, the program vendor identifies certain drugs that have available manufacturer assistance, and the plan then sets the copay at that amount or higher in order to extract—or "maximize"—the full value of the assistance. For example, if the maximum amount of annual copay assistance for a particular drug is $24,000, then the patient copay is set at $2,000 per month. Another aspect of these programs is that the drugs identified by the vendor are not treated as an EHB for purposes of ACA MOOP. If a plan classifies a drug as a non-EHB and a plan participant chooses not to enroll in the program and pays the increased copayment instead, that copayment would not accumulate towards the ACA MOOP. Similarly, even assuming that copay and other manufacturer's assistance would have to be counted toward the ACA MOOP under the rationale of the D.C. district court decision on copay accumulators, the ACA MOOP requirements only go to EHBs and the promotors of these programs would argue that even under that rationale they do not need to be counted because they are not EHBs.

- **Alternative Funding Programs:** Alternative funding programs ("AFPs") are facilitated by vendors who search for manufacturer's assistance or organizations that assist people in paying for expensive prescription drugs. These alternate funding sources can also be charities and are often set up by drug manufacturers. Qualifying for these funds usually requires that a person be uninsured or have no insurance for the prescribed drug (i.e., the drug is excluded from their health plan formulary) and often requires a household income equal to or lower than a specified amount. Plans with an AFP generally exclude certain drugs identified by the AFP vendor from the plan's formulary. However, the plans will sometimes cover a certain drug on an exception basis after a participant has requested funds from an alternate funding source and been denied. If a drug is excluded from a plan's formulary, then any payment for the drug and any assistance toward the payment for that drug would not count toward the ACA MOOP because it is not covered by the plan in the first instance. But, if covered on an exception basis, there is an open question of whether it is actually allowed to be excluded from MOOP.

These programs, in one form or another, have proliferated in recent years because they purport to allow plans to shift some of the cost for expensive specialty drugs onto the manufacturer while also sparing the participant from these costs. A critical feature of these programs is that the assistance—whether from the drug manufacturer or an alternate source—purportedly does not count toward the ACA MOOP. The plan uses vendors to help participants find and access assistance so that the participant pays nothing, and the plan also benefits because the longer it takes for the participant to reach the ACA MOOP, the longer the plan can shift some of the cost onto the drug manufacturer or alternate funding source.

Another aspect of the design of some of these programs is classifying the drugs in the program as non-EHBs. Under current ACA rules, self-insured group health plans do not have to cover EHBs, but if they do, then the participant's cost share must count towards the plan's ACA MOOP. Currently, self-insured plans have some flexibility in defining which drugs are EHBs. If the drug is not an EHB under the plan, the plan is not required to count any cost share towards MOOP, regardless of the source. This approach of classifying certain high-cost drugs as non-EHBs drives the plan participant to choose between a subsidized "free" drug through the copay maximizer or paying the higher copay, which doesn't help them to reach the ACA MOOP any faster. Under an AFP, the drug is not covered at all

(absent receiving a waiver from the plan), so the participant has the choice of enrolling in the AFP and getting the drug for free or paying the full cost of the drug. Again, under either alternative, the vendor's view is that nothing counts toward the ACA MOOP.

MOPPING UP THE MOOP: WILL ALL COVERED DRUGS HAVE TO BE CLASSIFIED AS EHBS UNDER A COPAY MAXIMIZER PROGRAM?

As detailed in our article on copay accumulators, HHS attempted to clean up the ACA MOOP issue in its 2021 Notice of Benefit and Payment Parameters ("NBPP") by allowing plans to disregard the value of drug manufacturer assistance for purposes of the ACA MOOP. That regulation adopted in the 2021 NBPP was vacated by the D.C. district court, and the issue of whether manufacturer's assistance must be counted toward the ACA MOOP is in a state of limbo, given the HHS nonenforcement position on the issue.

However, that still leaves the copay maximizer programs, which provide that if a participant does not enroll in the program and pays the higher copay, that copay still does not apply to ACA MOOP because the drug is not an EHB. On April 2, 2024, regulators finalized the 2025 NBPP, which requires that non-grandfathered individual and small group market plans covering prescription drugs in excess of the regulatory standard (the state benchmark standard or at least one drug in every United States Pharmacopeia (USP) category and class) to treat any additional drugs in the USP category and class as EHBs for purposes of the ACA MOOP (with a limited exception).

In the proposed 2025 NBPP, there was some question about whether the rule would apply to self-insured plans, which would effectively end the practice of classifying some drugs as non-EHBs. Regulators clarified in the preamble to the rule and in the FAQ About Affordable Care Act Implementation Part 66 ("FAQ Part 66") that this policy will not apply to self-insured plans under 2025 NBPP but that future rulemaking will be proposed to apply these same standards to large group market health plans

and self-insured group health plans. If that happens, self-insured plans could still impose higher cost-sharing requirements for more expensive drugs through their copay maximizer programs but would have to count any amount paid by the participant towards the plan's ACA MOOP.

In the preamble to the 2025 NBPP, regulators noted that "it is not apparent that [plans] are capable of readily explaining the rationale behind designations of 'non-EHB' for specific drugs to consumers in advance of their enrollment in the plan," adding that even if this rationale could be explained, "it is unreasonable to expect enrollees to be able to understand the complicated impacts that getting coverage for specific 'non-EHB' drugs would have on enrollee out-of-pocket costs and consumer protections." Although the policy does not technically apply to self-insured plans just yet, plans that exclude certain drugs from EHB as part of a copay maximizer program should take note of these signals from regulators.

COMPLIANCE CONCERNS FOR ALTERNATE FUNDING PROGRAMS

Even if self-insured plans had to classify all covered prescription drugs as EHBs, a plan could still exclude certain drugs from coverage altogether. Excluding drugs from the formulary is a common feature of AFPs, which access funds from alternate funding sources that are usually set up to help individuals who are either entirely uninsured or whose health plans do not cover a particular drug. Some AFP vendors require the plan to be amended to exclude certain drugs identified by the vendor, and the vendor then works with participants to apply for assistance. These alternate funding sources, however, have no obligation to the plan or to its participants, and assistance may be denied. The plan administrator may respond to a denial from an alternate funding source by overriding the exclusion and providing a tax-free reimbursement to the participant for the cost of the excluded drug. As beneficial as these AFP programs may be for controlling costs, they create a number of risks for plans.

TAX CONSEQUENCES

When a plan makes a reimbursement to a participant, Section 105 of the Code allows the reimbursement to be tax-free only if it is for an item or service covered under a written plan. If a drug is excluded from coverage by the written plan, the plan cannot make a tax-free reimbursement without violating Section 105. Thus, any reimbursement outside the provisions of the plan would be taxable, which must be reported on the employee's W-2, and all applicable federal income and employment taxes must be withheld and reported. Failures to properly administer these reimbursements could lead to a number of tax penalties, including a penalty of up to 2%-15% of the unpaid amounts (based on the length of the delay).

INADVERTENTLY CREATING A NEW GROUP HEALTH PLAN

Another health plan may be created when a tax-free reimbursement is provided outside of the primary group health plan. If the details of the AFP are disclosed to participants in a written document, and if tax-free reimbursements are provided as part of the AFP when requests for alternate funding are denied by the funding source, then it could be argued that the AFP itself is a separate group health plan. This outcome is not desirable because the AFP would presumably be subject to the same regulatory requirements, disclosure obligations, and tax regimes as any other group health plan, including ACA mandates.

ERISA VIOLATIONs

AFPs may also open plan fiduciaries to ERISA violations. ERISA requires plan fiduciaries to ensure plan assets, such as participant contributions, are used only to provide benefits under the plan (and to defray reasonable plan administration expenses). If a claim for an excluded drug is overridden under the AFP, and if the participant is reimbursed, tax-free, through the same claims account established by the employer to fund group health plan benefits, then arguably, plan assets have been used to fund an item outside of the plan. This would

also be a breach of fiduciary duty under ERISA. This risk applies even to self-insured plans without trusts. Self-insured plans funded through a Code Section 125 cafeteria plan are subject to a moratorium on the trust requirement (DOL Technical Release 92-01). Compliance with the moratorium allows employers to retain participant cafeteria plan contributions in the employer's general asset account as long as the employer ensures that such contributions are used solely to provide plan benefits (or to defray reasonable plan administration expenses). The DOL would likely view the claims account as constituting plan assets because it includes participant contributions.

How much of a risk is the reimbursement for non-covered items or services from the plan's claims account to the plan fiduciaries? If a breach of fiduciary duty occurs, a plan fiduciary—usually the employer—may be liable for the loss to the plan caused by the breach. The DOL could also impose a civil penalty of 20% of the amount recovered by the DOL, either through a settlement or an adverse court decision. This penalty would be imposed on the breaching fiduciary and any other person who knowingly participates in the breach.

Another issue for plans that cover certain drugs only when alternate funding is unavailable is the argument that the drug is technically still covered. This is problematic for a plan that uses an AFP vendor to assist participants with requests for such funds because representation on any application for alternate

funds that the participant has no coverage for the drug is arguably a misrepresentation. This may violate state laws and raise ERISA fiduciary issues.

NONDISCRIMINATION TESTING ISSUES

Not all plans with AFPs exclude the drugs entirely from coverage under the plan. Some plans are designed to allow coverage for certain drugs if the request for alternative funding is denied. This design raises a couple of other issues. First, organizations that provide alternate funding not only require (usually) that the person be uninsured or that the drug not be covered under the plan but also include income caps for eligibility. For example, an alternate funding source may only provide assistance to individuals with household incomes below a certain figure—a figure that is likely to be below the household income for highly compensated individuals. This could result in more dollars being used from the plan's claims account to pay for drugs for highly compensated individuals who will never qualify for alternate funding, which could skew the outcome of the Code Section 105(h) nondiscrimination testing to favor highly compensated individuals. In other words, certain drugs for lower-income employees are funded by an alternate funding source, but these same drugs are funded by the plan for highly compensated individuals. Discriminatory benefits are taxable to the highly compensated individuals and must be reported on W-2s.

LOCKED OUT BY THE ALTERNATE FUNDING SOURCE

Alternate funding sources (which are often the drug manufacturers) have caught on to many copay maximizer and AFP approaches, and it is common to see exclusions for individuals enrolled in copay maximizer programs or AFPs incorporated into assistance eligibility requirements or benefit levels. Some alternate funding sources go so far as to name certain vendors and programs in the exclusions. Similarly, some drug manufacturers do not extend copay assistance to individuals covered under plans with copay maximizers-type practices, while other drug manufacturers still provide some copay assistance for plans with maximizers, but at a significantly reduced amount. Again, ERISA fiduciary issues and state law misrepresentation issues may be raised if an AFP copay maximizer vendor assists a participant with an application for assistance when the vendor knows or should know that the application is not in accordance with the manufacturer's terms and conditions for that assistance.

WHAT TO MONITOR

Even though several of the compliance issues raised by these programs are murky due to a lack of clear guidance from regulators, they remain popular with plan sponsors because of the cost savings. Although there are no

clear-cut answers (yet), plan sponsors considering such programs will want to monitor the following:

- Ensure disclosure of copay maximizer or alternate funding program: These programs should be fully disclosed and explained to participants in the summary plan description. Programs that are outside of the plan may constitute a separate group health plan, leading to unintended compliance obligations.
- Tax-free reimbursement only for covered drugs: Drugs that have been specifically excluded from the plan should not be eligible for tax-free reimbursement from the plan.
- Special care for high-deductible health plan ("HDHP") participants: Although these programs are designed not to give ACA MOOP credit for manufacturer's assistance, keep in mind that, as discussed in more detail in our prior article, if credit is given, then HSA eligibility may be jeopardized. Rules for eligibility to contribute to an HSA forbid any coverage prior to meeting the deductible, which would include providing deductible credit for amounts paid by manufacturer assistance or an alternate funding source. For plans that do include such assistance in the plan's MOOP, administrative systems need to be implemented to track the deductible separately and exclude the value of the assistance from accumulating toward the deductible.
- Review how the program could affect nondiscrimination testing: Alternate funding sources may benefit lower-income participants, leaving the plan to pick up the cost for higher-income participants. This could affect the outcome of nondiscrimination testing for self-insured plans under section 105(h).
- Understand what kinds of representations the program vendor is making on the plan's behalf: Service agreements for some of these programs sometimes lack a full explanation of exactly what the vendor does. Plan fiduciaries need to be aware of any representations that vendors are making on behalf of the plan participant or the plan itself in requests for manufacturer assistance or alternate funding sources. ■

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