Example

- In the previous example—when adding on this new feature regarding EHBs—the PBM would have a lot of discretion to determine which drugs are EHBs
- The participant who opts out of the program will pay the 30-45% copay for the entire year. This would occur if the PBM determines that the drug is not an EHB
- Question—how does this program work in conjunction with other programs encouraging use of generic drugs?
  - These programs are aimed at expensive brand drugs, as those are the ones that have assistance programs.
  - What drug is dispensed if there is an expensive brand drug with assistance versus a lower cost clinical equivalent drug?
  - Assuming that the expensive brand is dispensed due to the assistance, will the drug be changed to a generic equivalent when the assistance runs out?

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Other Features—Patient Assistance Programs

- Rather than requiring an employee to sign up for coupon programs, some programs require employees to seek money from patient assistance programs (PAP) (sometimes referred to as alternative funding programs)
- The program requires that the company's major medical plan be amended to carve-out certain specialty drugs—i.e., stop covering certain prescription drugs. The process for a participant to obtain those specialty drugs is handled by the program.
- The program determines whether an employee could qualify for a PAP, which is a nonprofit organization that provides financial assistance to individuals who don't have health insurance or who are underinsured and cannot afford the specialty drug.
- In many cases, only lower-income individuals qualify for a PAP.
- If those lower-income individuals are unable to obtain financial assistance from a PAP, the company is to direct the program to "override" the denial and process the claim. Future claims for that specialty drug are directed back to the major medical plan for coverage. In other words, the major medical plan will cover the specialty drug if the employee does not qualify for a PAP.

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Maximizer Program

- Do any of these maximizer programs comply with the terms of the agreement between the PBM and the pharmaceutical company? Is that even addressed in the contract between those 2 parties?
- The employer cannot know the answer to these questions.
- If the pharmaceutical company sues the PBM stating that the PBM unlawfully accessed those coupons or PAP dollars, what will happen? Will the PBM seek those amounts back from the employer?
- We don't know the answer to these questions. To protect the employer and the plan, ask for indemnification.
    - If the PBM says no—push back and ask why.

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Concerns

- When a lower-income participant applies for financial assistance from a PAP, in many cases that person must attest to not having any insurance coverage for the specialty drug.
- However, for many programs, that is not a correct statement because if the participant does not qualify for the PAP, the claim is then covered by the major medical plan on an “exception” basis.
- Accordingly, the request by the company (through the program) for the participant to make this attestation to the PAP raises ERISA fiduciary issues.

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Concerns

- It seems likely that the program will quickly determine that higher income employees will not qualify for a PAP and their specialty drugs will be covered by the major medical plan.
- Lower-income employees who may qualify for a PAP will be required to engage in a more complicated process to obtain coverage for specialty drugs. Making it harder for lower-income employees to obtain coverage under the employer's major medical plan for their specialty drugs may fail the nondiscrimination rules under the Internal Revenue Code.
- These programs could also run afoul of the HIPAA nondiscrimination rules that bar discrimination based on health status.

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Concerns

- Some programs have an additional feature.
- For a lower-income employee, the program will initially cover some or all of the cost of specialty drugs under a “drug card” while it determines if the participant can qualify for a PAP.
- If this drug card covers the cost of prescription drugs prior to the deductible being met under a high deductible health plan (“HDHP”), this could cause that participant to be ineligible for a Health Savings Account (“HSA”).

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Concerns

- A vendor of a health plan must comply with the HIPAA privacy rules, including signing a business associate agreement.
- Some vendors pushing these programs state that they will not sign a business associate agreement.
- The failure to have a signed business associate agreement would be a violation of the HIPAA privacy rules.

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The Other J&J Case

- In May 2022, Johnson & Johnson ("J&J") filed a lawsuit against Save On SP, LLC ("SaveOnSP"), a copay assistance program, alleging that SaveOnSP illegally drained its co-payment coupon and manufacturer assistance programs offered by J&J to help patients afford high-cost drugs (Johnson & Johnson Health Care Systems, Inc. v. Save On SP, LLC)
- On January 25, 2023, the Court dismissed SaveOnSP's motion to dismiss, allowing J&J's claims to proceed
- Most recent filings in the case in 2024 relate to discovery disputes

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The Other J&J Case

- J&J states in the lawsuit that the ultimate goal of SaveOnSP's program is to increase its own fees. The SaveOnSP program had the following features:
  - Recategorizing a drug from "essential health benefits" to "non-essential health benefits," which then enables SaveOnSP to increase co-pay amounts beyond the ACA's annual OOPM; and
  - SaveOnSP over-inflated patients' copay amounts to the maximum
    - In J&J's complaint, J&J referenced a statement provided by a SaveOnSP representative, "if the amount of assistance per fill is $6,600: we would literally set the patient copay to $6,600, and you would save that amount on every fill."

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The Other J&J Case

- According to J&J's complaint, SaveOnSP operated a complex arrangement to capture copay assistance and other assistance programs – meant for patients – for it and its plan clients.
- J&J claims that this resulted in J&J paying more than $100 million in assistance than it otherwise would have to pay
- J&J claims that the assistance program was meant to assist those who did not have access to other drug coverage programs
- J&Js claims are state tortious interference and deceptive trade practices
- Rumored that some employers have received subpoenas related to this case

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AbbVie vs. Payer Matrix LLC

- In 2023, AbbVie sued Payer Matrix, alleging that Payer Matrix engaged in a “fraudulent and deceptive scheme to enrich itself by exploiting AbbVie’s PAP through the enrollment of insured patients into a charitable program not intended for them.”
- The complaint from AbbVie states, “Through acts of fraud and deceit, Payer Matrix knowingly maneuvers ineligible patients into AbbVie’s PAP—specifically, insured patients who should be receiving their medicine through their employers’ health insurance plans. Payer Matrix then charges the patients’ employers a substantial fee for reducing the employers’ health insurance costs through its scam on AbbVie’s PAP and other pharmaceutical manufacturers’ patient assistance programs.”
- In an amended compliant filed in August of 2024, AbbVie alleged that Payer Matrix markets a new “alternative funding” option to its plan sponsor clients that involves Payer Matrix and its partner “RxFree4me” coordinating the illegal importation of purported AbbVie medicines and other pharmaceutical manufacturers’ medicines from outside the United States.
- This case is on-going.

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Action Items

- When presented with these “cost savings” programs, ensure that you understand all aspects of the program
- Analyze the legal aspects of program
- Consider what representations are required to be made by participants
- Make sure that you understand the risks and are not just being sold the “savings” aspect of the program
- If an employer decides to adopt any of these programs, request indemnification

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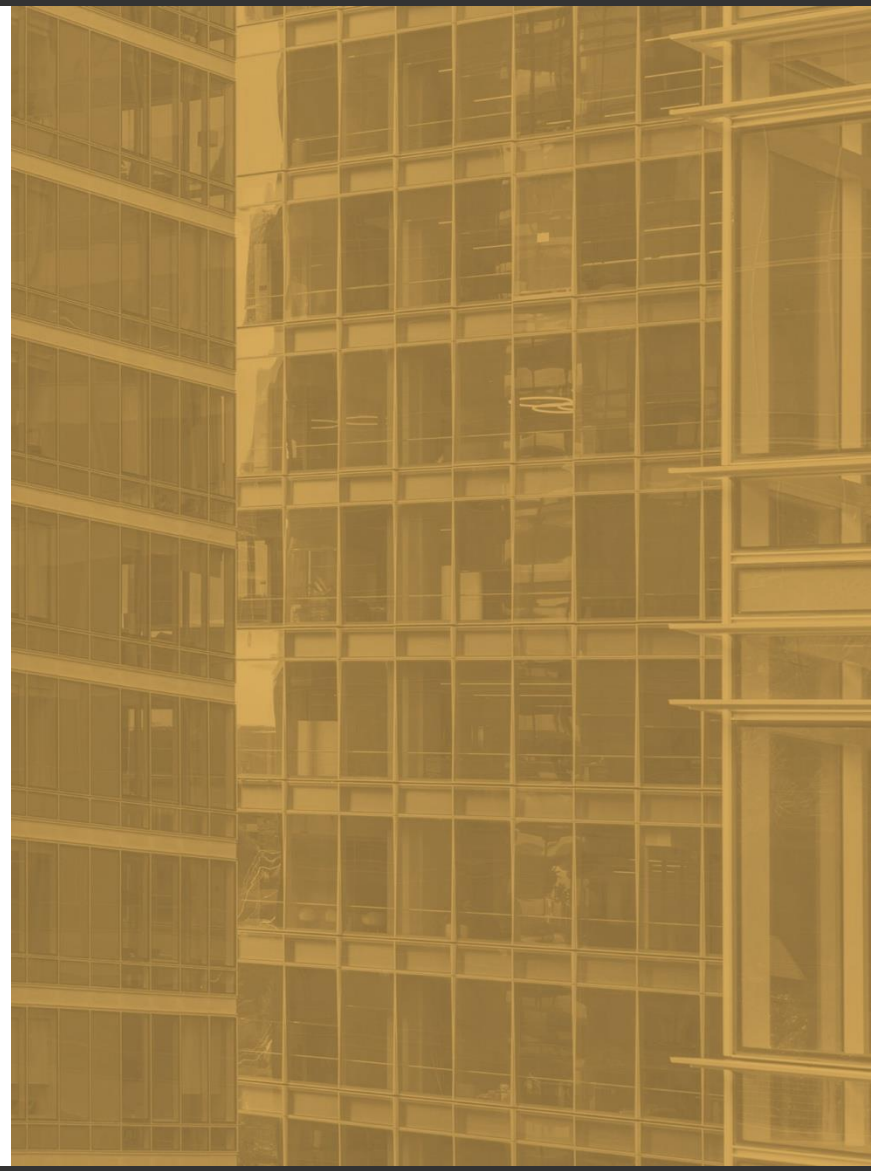

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