Copay Assistance Programs, Copay Accumulators, Copay Maximizers —What Are These?

Date: December 12, 2024

Mary Powell

PHONE: 415 788 3111 FAX: 415 421 2017 WEB: www.truckerhuss.com

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Overview

- Basics on PBMs
- Basics on ways PBMs make money from employer-sponsored plans
- Descriptions and examples of various savings programs
- Recent cases involving some of these programs

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BASICS ON PBMS

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Basics on PBMs

- It is important to understand how Pharmacy Benefit Managers (PBMs) work, so you can understand who is designing these various copay programs
- We generally think of PBMs as:
  - Entities that administer the prescription drug portion of a health plan
  - Middlemen between health plans/consumers and drug companies
  - The entity that negotiates drug prices and creates drug formularies
- PBMs negotiate with pharmaceutical companies for rebates but the PBMs also negotiate with pharmacies for fees & discounts
- Employers often do not understand the terms of the contracts, or the amount of direct/indirect compensation paid to PBMs

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PBMs

- The parties:
  - PBM
  - Pharmacy
  - Employer
  - Group Health Plan (GHP)
  - Pharmaceutical Company and
  - Wholesaler
- Three PBMs control over 80% of the GHP market: (1) Express Scripts (Cigna business), (2) CVS/Caremark (owns Aetna) and (3) OptumRx (business of UnitedHealth Group)

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PBMs

- For an employer-sponsored GHP, the employer (or plan) contracts with a PBM for it to manage and administer the prescription drug portion of the plan
- The PBM receives fees for providing services such as creating a network of pharmacies and administering claims and appeals
- Separately, the PBM enters into contracts with pharmacies that dispense the drugs, and those contracts address the amount the pharmacies will be paid for the drugs dispensed to the GHP participants

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PBMs

- The pharmacies negotiate upstream in the supply chain through agreements with wholesalers. Wholesalers supply and set the wholesale rates at which pharmacies obtain the drugs they dispense
- The wholesalers themselves negotiate to buy the drugs from the manufacturers
- Once the drugs are in the pharmacies, these drugs are subsequently distributed to consumers, such as GHP participants
  - Participants often pay a copay or coinsurance amount
  - With the rise of HDHPs, participants in HDHPs pay the “full cost” until the deductible is met

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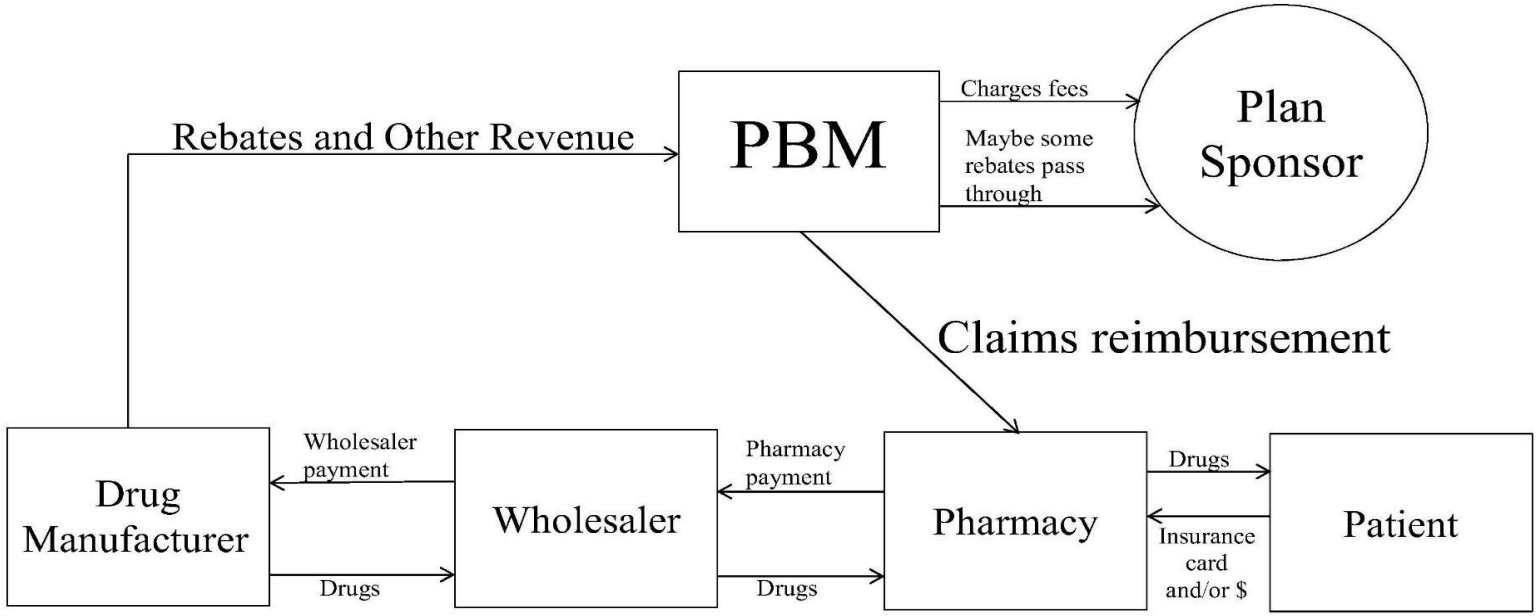
PBMs



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WHERE THE MONEY IS MADE

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Where the Money is Made

- There are numerous ways PBMs make money, such as:
  - Spread Compensation
  - Formulary Fees
  - Market Share Fees
  - Drug Reclassification
  - Multiple MAC lists
  - Rebates
  - Many more ways!
- Why does this matter for this discussion? Be mindful about additional costs that are charged for these copay programs, given the numerous ways the PBMs already make money from GHPs

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Spread Compensation

- What is spread compensation?
- A PBM contracts with a GHP to obtain drug prices for some percentage off the AWP
  - AWP is the average wholesale price
- AWP bears **no connection** to the actual price an entity will pay for those drugs. It is a "sticker" price that is set very high—and is often increased each year
- The PBM has a separate contract with the pharmacy networks to reimburse them based on a percentage of the AWP (or some other formula) that differs from the discount offered to plan sponsors

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Spread Compensation

- EXAMPLE:
  - PBM has a contract with a pharmacy chain to reimburse the pharmacy for a drug that it dispenses at the price of $300, but the PBM separately charges the GHP $2,000
  - The $1,700 differential is referred to as the “spread compensation” which the PBM retains as profits from the transaction
  - The spread can be A LOT of money
  - The amount of this spread compensation is NOT DISCLOSED to the employer/plan sponsor of the GHP

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Rebates

- What is a rebate? A rebate is a discount on a medication that a drug manufacturer gives to a PBM in return for the PBM agreeing to place the drug on a formulary
- PBMs receive rebates from drug manufacturers for the placement of their drugs on a formulary
- Some experts believe that on average, a third of the net price paid for medications is attributable to those rebates—meaning the cost to the patient may be 1/3rd higher due to rebates (IMS Institute for Healthcare Informatics)
- The current system incentivizes companies to push the list prices higher (such as the AWP), only to rebate money later on the back end (FDA Commissioner, Senate Hearing)

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Rebates

- EXAMPLE:
  - A drug manufacturer pays a PBM a rebate or incentive to place a drug on its formulary
  - This steers participants to purchase this drug since it is on the approved formulary for the plan
  - This rebate structure increases the PBM's compensation because often only those drugs on the formulary are covered by the plan
  - A question to consider: is the amount of the rebate one of the main drivers of whether a drug is on a formulary?

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Rebates

- EXAMPLE OF IMPACT:
  - A brand drug is placed high on a formulary
  - The rebate for that drug is $200
  - A generic is introduced into the market, that costs far less than the brand
  - The pharmaceutical manufacturer increases the rebate on the brand drug
  - The amount that the PBM can make on the spread compensation for the generic is less than the rebate it will receive for the brand drug
  - The PBM does not add the generic to the formulary

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Rebates

- An employer may think it doesn't need to worry about this structure since it receives 90%+ of the rebates
  - Consider:

    (1) does the employer really receive all the rebate payments?
    - Very unlikely due to how the term "rebates" are defined in the PBM agreement

    (2) are there other amounts paid to the PBM by the manufacturer that are relabeled and therefore are no longer considered a "rebate"?

    (3) should a lower cost drug be on the formulary?

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ERISA FIDUCIARY OBLIGATIONS

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Fiduciary Obligations

- Consider your fiduciary obligations when assessing these copay programs
- Who is a fiduciary?
  - A person (either an individual or an entity) is a fiduciary to the extent the person has any discretionary authority, control or management of an ERISA-covered plan (such as its administration, operations or assets) (ERISA §3(21))
- In many cases, the employer/plan sponsor is the ERISA Plan Administrator—which is a fiduciary role
- Under law, the failure to comply with fiduciary obligations can cause liability—both personal and to the company that sponsors the plan (assuming it is a fiduciary of the plan)

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Fiduciary Obligations

- The primary responsibility of fiduciaries:
  - Run the plan solely in the interest of participants and beneficiaries and for the exclusive purpose of providing benefits and paying plan expenses (the Exclusive Benefit rule)
  - To act with the care, skill, prudence, and diligence that a prudent person acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims (the Prudent Expert rule)
  - Follow the terms of plan documents
  - Avoid conflicts of interest and prohibited transactions

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THE “SAVINGS PROGRAMS”

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Savings Programs

- Once you understand how PBMs work, you can better understand the various “savings” programs that are offered by PBMs
- There are numerous “cost savings” programs
- Be critical of the ones where the PBMs make additional money
- The next few slides will cover:
  - Copay assistance programs
  - Copay accumulators
  - Copay maximizers
  - Non-essential health benefit programs
  - Examples of programs

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Copay Assistance Programs

- Phase 1—the pharmaceutical companies start off the game!
- For certain high-priced specialty and brand drugs, pharmaceutical manufacturers offer discount cards, coupons, and other forms of assistance to help participants afford the medication
  - This is often referred to as a copay assistance program
- Essentially, the drug manufacturer covers a portion of the cost-sharing obligations (i.e., copayments, coinsurance or deductibles) during the year until the participant's out-of-pocket maximum (OOPM) is met
- After the participant's OOPM is met, the health plan is responsible for covering the full cost of the drug for the remainder of the plan year
- Why is this done?
  - So that participants will purchase the brand specialty drug and not the generic equivalent

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Copay Accumulators

- Phase 2—the plan sponsors get in the game
- In response to copay programs, many health plans adopted copay accumulators
- This program makes it so that manufacturer copay assistance payments no longer count toward a participant's deductible or other out-of-pocket costs

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Copay Accumulators—Applicable Law

- Prior to 2019, federal law was silent on whether these copay adjustment programs were permitted.
  - While the applicable ACA regulations defined "cost sharing," those regulations did not specify whether manufacturer assistance must apply towards the ACA's cost sharing limits.
- In the 2020 Notice of Benefit and Payment Parameters (NBPP), CMS stated that it would permit plans to exclude the value of manufacturer assistance from the ACA's annual OOPMs "for specific prescription brand drugs that have an available and medically appropriate generic equivalent." CMS also noted that if there was not a medically appropriate generic equivalent available, then the plan was required to apply the manufacturer assistance towards the member's OOPM.
  - This was difficult for plans to administer, and CMS received a lot of negative feedback on this guidance
- CMS stated in the 2021 NBPP that to the extent consistent with state law, manufacturer assistance may be, but is not required to be, applied towards annual cost sharing limits
- In essence, the 2021 NBPP gave plans the discretion to either count, or not count, such assistance "toward the annual limitation on cost sharing"

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2023 Case—HIV + Hepatitis Institute v. HHS

- Three patient-advocacy groups sued CMS and HHS to invalidate the rulemaking from the 2021 NBPP that allowed health plans to operate copay accumulator programs, arguing that the rule violated the ACA
- The plaintiffs moved for summary judgement, arguing that the 2021 NBPP was unlawful and must be set aside for various reasons, including that it conflicted with the ACA's statutory definition of "cost sharing," and the 2021 NBPP is arbitrary and capricious.
- In September of 2023, the court granted plaintiffs' motion for summary judgement and vacated the 2021 NBPP
- The court focused on the fact that based on the agencies' interpretation, the health plan would have the ability to choose the meaning of "cost sharing" at their discretion
  - "…the issue here is not that the agencies have not yet definitively interpreted the definition of "cost sharing"; it is that they have authorized two courses of conduct based on two fundamentally contradictory readings of that definition . . ."
- The court remanded the matter to the agencies for further guidance.
- We are still awaiting guidance from the applicable agencies about copay accumulators

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Maximizer Program

- What is a copay maximizer program?
- Basic Copay Maximizer Programs. The participant's cost-sharing "obligation" for certain drugs is increased to capture financial assistance available from a drug manufacturer.
  - Are participants cost-sharing amounts actually increased for the participant?? In many cases, the answer is no.
  - The participant will still have something like a $25 copay, but the PBM system will change this on the backend so that the pharmaceutical company sees a much higher price owed by the participant
- "HDHP-Compliant" Copay Maximizer Programs. These programs operate in the same manner as the basic copay maximizer programs but do not begin applying drug manufacturer assistance until after the deductible is satisfied.

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Maximizer Program Example

- The program applies to a participant who is enrolled in a health plan
- The participant is pushed to sign up for manufacturer copay programs
- The participant must use the PBM specialty pharmacy
- If the participant opts out of the program, they are responsible for 30-45% of the cost share
- For an enrollee in the program, he has a zero coinsurance, even if there is no manufacturer assistance for the specific drug (with the exception for an HDHP until the deductible is met)
    - The PBM is changing the cost share on the backend of the system to capture the maximum amount of the pharmaceutical company coupon
- There is a per employee per month (PEPM) fee to be paid by the employer to the PBM for this program
    - Worse is if there is a “savings fee” applied

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More Complex Programs

- Adding on to the program above, many of the drugs will not be considered essential health benefits (EHBs), so amounts paid by the participant who opts-out of the program never accumulate to the OOPM
- What is an EHB?
- Affordable Care Act Section 1302(b) - ". . . the Secretary shall define the essential health benefits, except that such benefits shall include at least the following general categories and the items and services covered within the categories . . . Prescription drugs."
- HHS Bulletin December 16, 2011 – HHS intends to propose that essential health benefits are defined using a benchmark approach. Under the department's intended approach announced today, states would have the flexibility to select a benchmark plan that reflects the scope of services offered by a "typical employer plan."
- 45 CFR 156.122(a)– "A health plan does not provide essential health benefits unless it…covers at least the greater of: (i) One drug in every United States Pharmacopeia (USP) category and class; or (ii) The same number of prescription drugs in each category and class as the EHB-benchmark plan."

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HHS

Possible change to the EHB rules in the future—all drugs on the formulary are EHBs for large group health plans. (We question whether this will be the direction taken by the Trump Administration.)

Proposed Notice of Benefit and Payment Parameters for 2025 and FAQ Part 66. The FAQ states, "In the proposed HHS Notice of Benefit and Payment Parameters (NBPP) for 2025 (proposed 2025 NBPP), HHS proposed to amend 45 CFR 156.122 to codify that prescription drugs in excess of those covered by a State's EHB-benchmark plan are considered EHB…comments received in response to the EHB Request for Information issued in 2022 included a significant number of requests from interested parties to clarify the applicability of this policy in rulemaking, particularly as it relates to some plans in the individual, small group, and large group markets that have developed programs to provide coverage of some drugs as 'non-EHB,' outside of the terms of the rest of the coverage.

After consideration of comments on the proposed 2025 NBPP, HHS is finalizing the amendment to 45 CFR 156.122 in the final HHS NBPP for 2025 (final 2025 NBPP) with respect to issuers of non-grandfathered individual and small group market plans that are subject to the requirement to provide EHB."

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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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Contact

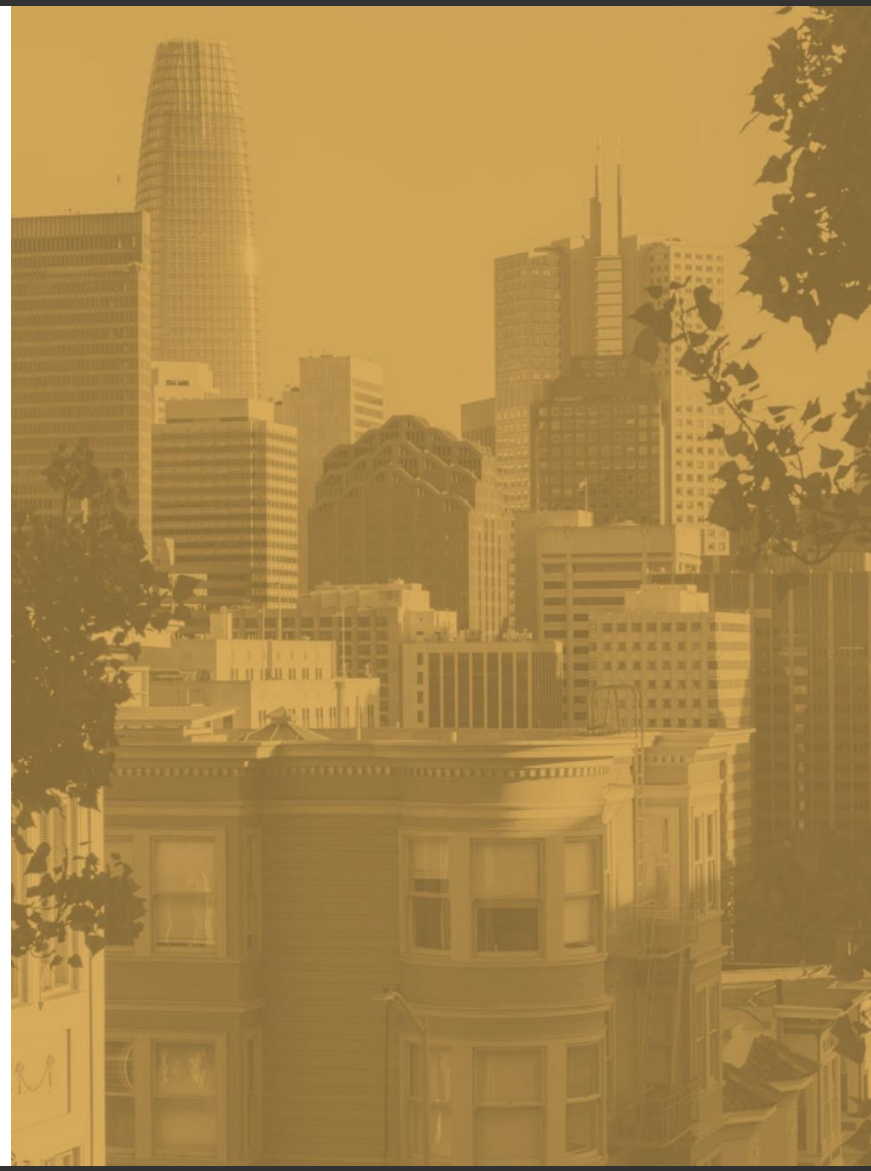
Mary Powell, Esq.

Trucker Huss, APC

135 Main Street, 9th Floor
San Francisco, CA 94105
(415) 788-3111

mpowell@truckerhuss.com

www.truckerhuss.com



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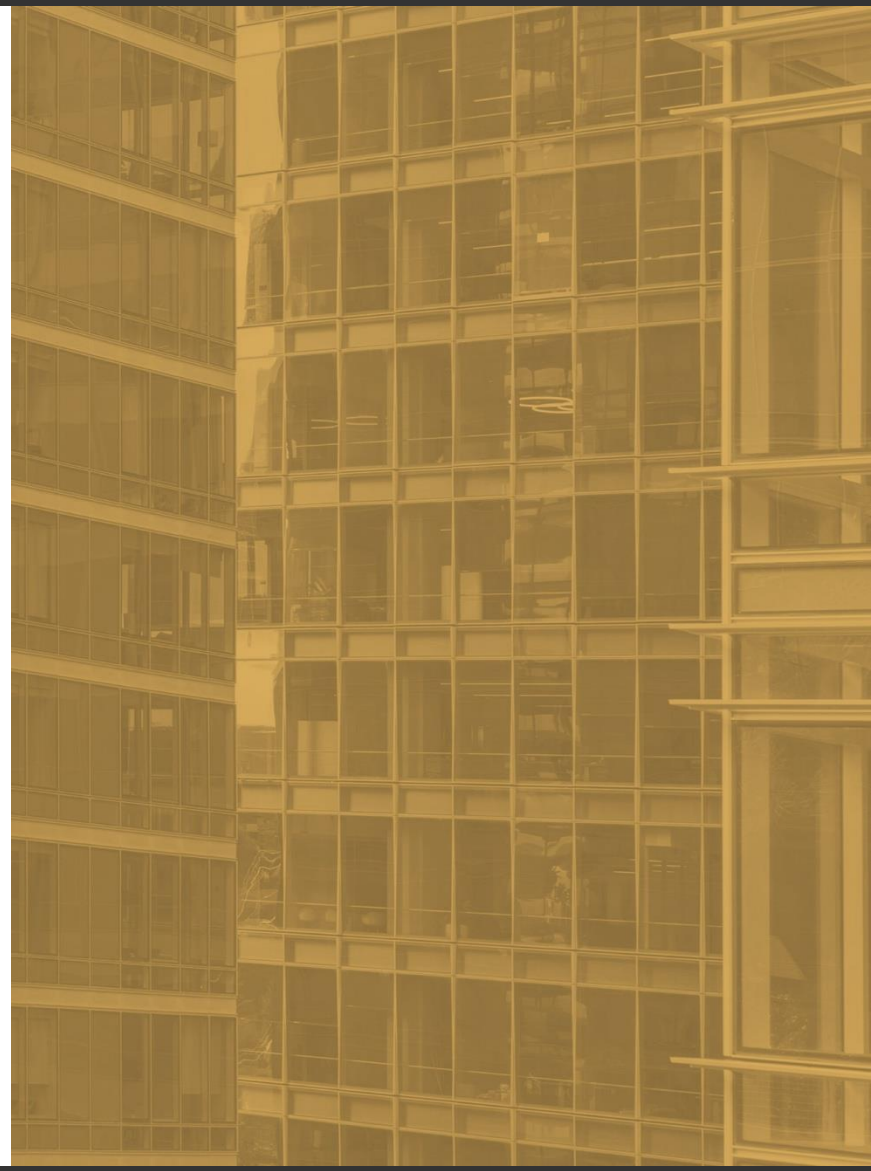

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