

Pharmacy Benefit Managers - What ERISA Fiduciary Obligations and Duties Relate to Prescription Drug Plans?

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Topics To Be Discussed

- ★ What is a Pharmacy Benefit Manager (PBM)?
- ★ How do PBMs make money?
- ★ Contract terms
- ★ Transparency Rules
- ★ Fiduciary obligations related to PBM contracts and services
- ★ Recent Cases

THE BASICS ON PHARMACY BENEFIT MANAGERS

What is a PBM?

- ✦ We generally think of the Pharmacy Benefit Managers (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 contract or the amount of direct/indirect compensation paid to the PBMs

What is a PBM?

- ✦ Employers rely on the PBMs to administer their prescription drug plans
- ✦ PBMs claim that they create savings for the plans and the plan participants
- ✦ The savings have mostly not materialized for the employers—employers pay far too much for prescription drugs
- ✦ PBMs have a conflict of interest but employers have difficulty in obtaining any information about that due to the lack of transparency
- ✦ Employers need to understand the parties and the terms of the contract
- ✦ We understand that this is a big lift for employers

Understanding a PBM Contract

- ★ The parties:
 - > PBM,
 - > Pharmacy,
 - > Employer,
 - > Group Health Plan,
 - > Pharmaceutical Company, and
 - > Wholesaler
- ★ For ERISA-covered plans, the main players are the employer, the group health plan and the PBM

PBMs—A Powerful Group

- ✦ Three PBMs control close to 80% of the GHP market: (1) Express Scripts (Cigna business), (2) CVS/Caremark and (3) OptumRx (business of UnitedHealth Group)
- ✦ The PBMs make an enormous amount of profit each year. For example, it is reported that 2/3rds of Cigna's \$110 billion in revenue last year came from its Express Scripts subsidiary
- ✦ PBM profits have increased year-over-year and by some estimates, have grown over 600% since 2003
- ✦ An entity that does not do the research for the drugs or manufacture the drugs—has massive growth each year
- ✦ How does a plan sponsor know how much it pays the PBM?

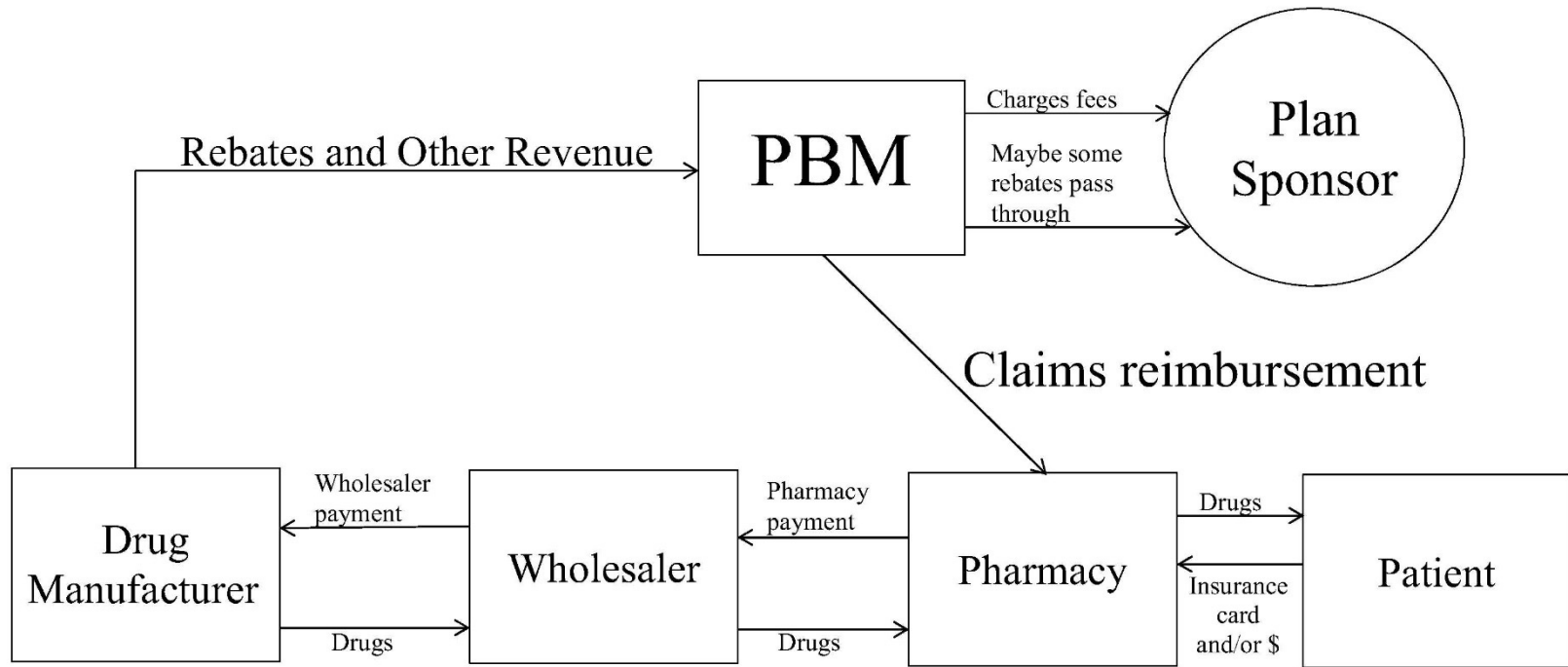
The Main Players

- ✦ 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, a 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

The Main Players

- ✦ 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 co-pay or coinsurance amount
 - > With the rise of HDHPs, participants in HDHPs pay the “full cost” until the deductible is met

CHART



WHERE THE MONEY IS MADE

Where the Money is Made

- ★ There are numerous ways the PBMs make money, such as:
 - > Spread Compensation
 - > Formulary Fees
 - > Market Share Fees
 - > Drug Reclassification
 - > Multiple MAC lists
 - > Rebates
 - > Many, many more ways!

Where the Money is Made

- ★ One source is through “spread compensation”
- ★ A PBM contracts with a GHP to obtain drug prices for some percentage off AWP
 - > AWP is the average wholesale price
- ★ AWP bears **no connection** to the actual price any entity will pay for those drugs. It is a “sticker” price that is set very high
- ★ The PBM has a separate contract with the pharmacy networks to reimburse based on a percentage of AWP (or some other formula) that differs from the discount offered to employer-sponsors

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 \$1,000
- > The \$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-sponsor of the GHP

Rebates

- ✦ PBMs receive rebates from drug manufacturers for the placement of their drugs on a formulary
- ✦ A rebate is a discount on a medication a drug manufacturer gives a PBM in return for the PBM agreeing to place the drug 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, 2016)

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 PBMs compensation because often only those drugs on the formulary are covered by the plan
- > A question is if one of the main drivers of whether a drug is on a formulary is the amount of the rebate

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 company 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

Rebates

- ✦ An employer may think it need not worry about this structure since it receives 90%+ of the rebates
 - > Consider:
 - (1) does the employer really receive all of the rebate payments?
 - (2) are there other fees 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?

CONTRACT TERMS

Contract Terms

- ★ When the employer has a better understanding of how the PBM receives direct and indirect compensation, it is in a better place to negotiate a contract
- ★ A good first step is to have a solid understanding of contract terms and pricing
- ★ Do NOT get overwhelmed by the terms in the contract. You are smart and can figure this out!
 - > You should also hire experts to help you!!

AWP

- ✦ A lot of the pricing provisions in the contract are based off AWP
- ✦ A common definition of AWP is something like the following:
 - > **"AWP"** means the "average wholesale price" of the Covered Product on the date dispensed, as set forth in the current price list in recognized sources such as Medi-Span's Master Drug Database file or any other nationally recognized reporting service of pharmaceutical prices as utilized by PBM as a pricing source for prescription drug pricing
- ✦ If the contract is going to use AWP, there needs to be a specific, strict definition of that term in the contract
- ✦ This definition leaves too much discretion to the PBM

AWP

- ✦ Question if AWP is the right “benchmark” for determining the costs of drugs
- ✦ This is raised in the Johnson & Johnson complaint (which we will discuss later)
- ✦ The difference between AWP and the pharmacy’s actual acquisition cost can be substantial

AWP

- ✦ CMS compiles a National Average Drug Acquisition Cost (NADAC) database
- ✦ This is a database that uses survey data to determine the average acquisition cost for many drugs
- ✦ An example in the J&J complaint:
 - > For a generic HIV antiviral drug, NADAC has the acquisition cost of about \$181 dollars for a 90-day supply. The complaint states that the plans paid the PBM \$1,629 for the same 90-day supply
 - > Looking at the cash price for someone who is not insured—such as looking at the website for CostPlus, Rite Aid, etc.—the average cash price for someone with no insurance for that 90-day supply is about \$200

MAC

- ✦ For generics, the difference between the pharmacy's actual acquisition cost and AWP may have an even larger disconnect, because PBMs generally don't pay the pharmacy based on AWP, but rather the "Maximum Allowable Cost" or MAC
- ✦ A common contract provision will state something like the following:
 - > **"Maximum Allowable Cost" or "MAC"** means the unit price that has been established by PBM for a drug with multiple generic sources included on the MAC drug list applicable to client, which list may be amended from time to time by PBM in maintaining its generic pricing program
- ✦ This definition allows too much discretion to the PBM

MAC

- ★ A suggestion is to request that the same MAC list pricing used for a non-network pharmacy be used for the pricing in the contract
- ★ The PBM will likely have a different MAC list for different pharmacies
- ★ The MAC prices for their own pharmacies may be higher than for non-network pharmacies

Rebate

- ★ How is the term “rebate” defined in the contract?
- ★ Example of a definition in a PBM contract, “Rebate means the rebates collected by the PBM in its capacity as a group purchasing organization for the client from various pharmaceutical companies that are attributable to prescriptions **dispensed to members**, but **specifically excluding** any rebates paid with respect to utilization of specialty drugs.”
 - > What about fees it receives for the overall increased sale of drugs?
 - > **Excluding specialty is big \$\$**

Rebates

- ✦ What if the PBM contract with a drug manufacturer gives rebates another name — like administrative fees or health management fees?
 - > the PBM will arguably eliminate its obligation to pass on any of this money
- ✦ What if the rebate is paid on a basis that is not directly attributable to the clients' drug purchases? For example, if a PBM/manufacturer contract says the manufacturer will pay \$10M in rebates to the PBM if the PBM increases the manufacturer's market share for xxx drug by xxx percent?
 - > Those rebates will arguably not be directly attributable to any particular client

Rebates

- ✦ Carefully review the definition of rebate
- ✦ Watch out—and push back—against provisions that state that the employer does not receive any portion of the Manufacturing Administrative Fees (MAFs)
 - > This is big money
 - > Generally, employers are only successful in getting MAFs as part of an RFP process

Brand and Generic

- ★ These are key terms—pricing and guarantees are based on these terms
- ★ These terms need to be locked down. Example of a current definition in a contract:
 - > “**Generic drug:** The term “generic drug” shall mean a multisource drug set forth in a nationally recognized source, as reasonably determined by the PBM, that is available in sufficient supply from multiple FDA-approved generic manufacturers of such drugs.”

Brand and Generic

- ✦ What does that mean?
- ✦ Can you audit against this definition?
- ✦ Under the above definition, the PBM is likely to categorize all single-source generics as brands
- ✦ We suggest that the definition of generic state what reporting service is being used (such as MediSpan) **and the exact codes** used for determining which drugs are generics
 - MediSpan and First Databank do not use the same codes
- ✦ Push to have a provision in the contract that states that once a drug is categorized, it stays in that category—a consistency provision

Brand and Generic

- ✦ Some PBM contracts allow the PBM to classify drugs for one purpose in one way, and for another purpose in another way
- ✦ When it is in the PBM's interest to classify more drugs as brands — for instance, when determining how to invoice clients — the PBM uses its ambiguous and discretionary definitions to shift drugs into the brand category
- ✦ When the PBM wants to make its generic substitution rate appear greater, it may reclassify drugs that were invoiced as brands to be re-characterized as generics
- ✦ If a contract requires the PBM to pay a specified rebate for brand drugs, it could reclassify drugs that were invoiced as brands to be re-characterized as generics for the purpose of calculating rebates

Specialty Drugs

- ✦ PBMs generally require plans to pay a very high price for specialty drugs
- ✦ Specialty drugs can often account for over 50% of the prescription-drug plan's overall spend
- ✦ Many PBMs use their own mail-order specialty pharmacies
- ✦ GHPs will incentivize employees to use these specialty pharmacies, such as by having lower co-pays, because they are promised more cost-savings from the PBM

Specialty Drugs

- ✦ There is not a clear definition of what a “specialty drug” is for health plans
- ✦ Which drugs are on this list should be negotiated between the plan sponsor and the PBM
- ✦ Before you sign the PBM contract, it would be a good idea to have the list reviewed by a prescription drug consultant
- ✦ Another suggestion is to have a contract term that states that you have the right to see how the list changes each quarter—and the right to make changes/deletions to that list

Scope of Services

- ✦ Consider all of the services being provided by the PBM
- ✦ As an example, consider if it is beneficial to carve Utilization Management (UM) away from the PBM and having that performed by a different third party
 - For example, step therapy is a UM program that requires members to try a low-cost medication for select drug classes before a higher-cost medication is dispensed
- ✦ A PBM may have a conflict in interest with regards to the drugs covered under the plan—this can impact the effectiveness of the UM program
- ✦ The idea of carving up the PBM and outsourcing formulary design, UM, case management, specialty pharmacies, etc. is worth consideration

Audit Rights

★ Rebate audit rights:

- > Include the right to audit rebates and for all needed information to be accessible for the audit

★ Audit timeframes:

- > Specify that the PBM is to provide the requested data within 30-45 days of the request

★ Auditor of choice:

- > The plan sponsor should have the right to choose the auditor—and not be limited to select firms.
Alternatively, put the names of preapproved auditors in the contract

Audit Rights

★ Audit expenses:

- > Each party should be responsible for its audit expenses. The PBM should not charge the employer for the time it spends in collecting the requested data

★ Broad audit rights:

- > The employer should be able to audit the PBM to enforce any of its rights under the contract—and not just limited things like rebates only. The employer should be able to audit for performance guarantees, utilization management programs, etc...

RFP

- ✦ To get these terms, you need to run an RFP, with the help of experts
- ✦ Consider providing sample contract terms to the PBMs at the time of the RFP and have them sign an agreement that they will include such terms in any contract awarded
- ✦ A PBM may tell you that it will be transparent and pass on all rebates, however, when presented with strict terms, the PBM may not be willing to abide by those terms

RFP

- ★ As part of an RFP, consider the different types of models for PBM pricing
 - > The model often used by an employer (plan sponsor) allows for the spread pricing and includes rebate checks
 - > Pass-through pricing has the plan pay exactly (or very close) what the PBM pays the pharmacy for the drug. All rebates and other financial benefits are passed on to the plan sponsor. The plan pays the PBM an administrative fee for various services and not any other amounts
 - HIGHER admin fees and LOWER rebates may be a better deal for the employer

Experts

- ✦ We suggest that you obtain assistance of experts
 - > These plans are a huge expense for employers
 - > Get the right resources to obtain better pricing
- ✦ If your PBM contract has many of these issues, consider if the consultant that you have been using is the right one
- ✦ Consider during which steps you should include your legal counsel—often you include us late in the process
 - > RFP development (proposed contract terms, definitions, etc.)
 - > Proposal evaluation (reviewing responses from the PBM)
 - > Contract negotiations (review if what was promised in the RFP is actually in the contract)

TRANSPARENCY RULES

Cost Comparison Rules

- ★ Regulations under the ACA require plans and insurers to disclose individualized cost-sharing information upon request, to a participant, beneficiary, or enrollee (or his or her authorized representative), including an estimate of the individual's cost-sharing liability for covered items or services furnished by a particular provider
- ★ Plans and insurers are required to make such information available on an internet-based self-service tool and, if requested, on paper

Cost Comparison Rules

- ✦ An initial list of 500 shoppable services (as determined by the agencies) had to be available on the internet-based self-service tool for plan years that began on or after January 1, 2023
- ✦ The remaining items and services must be available through these self-service tools for plan years that begin on or after January 1, 2024
- ✦ It appears that the information made available from this rule was used in the J&J complaint

Machine-Readable Files

- ✦ Requirement for the plan to make available to the public on an internet website an in-network machine-readable file and an out-of-network allowed amount machine-readable file that includes the information required under the regulations
 - > These files are updated monthly
- ✦ The machine-readable file regulations for prescription drugs are stuck in litigation
- ✦ The current format of this information makes a lot of it unusable. New rules will likely be proposed soon to fix this.

Responsible Fiduciary Rule—ERISA § 408(b)(2)

- ✦ The CAA requires “covered service providers” to disclose their “direct” and “indirect” compensation received during the term of the contract or arrangement to a “responsible plan fiduciary” of a “covered health plan”
- ✦ A “covered service provider” means a service provider that enters into a contract or arrangement with the covered plan and reasonably expects \$1,000 or more in compensation, direct or indirect, to be received in connection with providing **brokerage or consulting services**
- ✦ A “covered plan” means an ERISA-governed group health plan, including major medical plans, vision plans, dental plans, health reimbursement arrangements and flexible spending accounts but not qualified small employer health reimbursement arrangements (QSEHRAs)

Responsible Fiduciary Rule—ERISA § 408(b)(2)

- ★ The rule applies to contracts or arrangements entered into, extended, or renewed on or after December 27, 2021
- ★ A “responsible plan fiduciary” is to review the compensation disclosure
- ★ A “responsible plan fiduciary” means a fiduciary with authority to cause the covered plan to enter into, or extend or renew, the contract or arrangement
- ★ Remember this on-going obligation

Responsible Fiduciary Rule—ERISA § 408(b)(2)

- ✦ The DOL takes a broad view of “consulting” and “brokerage” services
- ✦ Consulting means that the entity reasonably expects to receive indirect compensation or direct compensation related to:
 - > the development or implementation of plan design,
 - > insurance or insurance product selection (including vision and dental),
 - > recordkeeping,
 - > medical management,
 - > benefits administration selection (including vision and dental),
 - > stop-loss insurance

Responsible Fiduciary Rule—ERISA § 408(b)(2)

- > pharmacy benefit management services,
 - > wellness design and management services,
 - > transparency tools,
 - > group purchasing organization agreements and services,
 - > participation in and services from preferred vendor panels,
 - > disease management,
 - > compliance services,
 - > employee assistance programs, or
 - > third party administration services
- ★ The definition of brokerage services is similar, but it focused on the placement of those services/service providers

DOL Guidance—FAB 2021-03

- ✦ ...the Department is of the view that a significant goal of the new disclosure requirements is to enhance fee transparency, especially for service arrangements that involve the receipt of indirect compensation as defined in ERISA section 408(b)(2)...Accordingly, in light of this goal and taking into account the prohibited transaction consequences of a disclosure failure, service providers who reasonably expect to receive indirect compensation from third parties in connection with advice, recommendations, or referrals regarding any of the listed sub-services in section 408(b)(2)..., should be prepared, if the Department is auditing their 408(b)(2)(B) compliance, to be able to explain how a conclusion that they are not covered service providers is consistent with a reasonable good faith interpretation of the statute.

Responsible Fiduciary Rule—ERISA § 408(b)(2)

- ✦ The rule amends ERISA §408(b)(2) to make these disclosures a part of the “service provider” exemption to the prohibited transactions rules
- ✦ In general, the prohibited transaction rules prohibit fiduciaries from engaging in transactions with certain parties in interest
 - Transactions prohibited by these rules include the payment of compensation to parties in interest
- ✦ ERISA §408(b)(2) furnishes a statutory exemption from the prohibited transaction rule that covers “any contract...made with a disqualified person for...services necessary for the establishment or operation of the plan, **if no more than reasonable compensation** is paid therefore”

Responsible Fiduciary Rule—ERISA § 408(b)(2)

- ✦ The rule requires that they entities disclose a LONG list of the types of compensation received
 - > Review the specific list & send the consultants and brokers a letter requesting this information
- ✦ This was an issue in the J&J complaint
- ✦ Consider if the PBM is a consultant
 - > Does the PBM consultant on plan design?
- ✦ WE SUGESST THAT YOU ASK FOR INFORMATION ON ALL DIRECT AND INDIRECT COMPENSATION RECEIVED FROM THE PBM
 - > Even if you cannot obtain all of it, document that you asked for it!

FIDUCIARY OBLIGATIONS

Why Care?

- ★ Employers pay too much for prescription drugs
 - > This takes away from your budget to provide other benefits
- ★ Conducting a prudent and robust RFP process and monitoring the PBM is part of your fiduciary obligations

The Cast of Characters

- ★ The ERISA Plan—a separate legal entity
- ★ The Plan Sponsor—in many cases, the employer
- ★ Plan Fiduciaries—named fiduciaries (fiduciaries named in plan document, which will often include the employer) and others deemed to be fiduciaries based on the function they perform (“functional fiduciaries”)
- ★ Participants and Beneficiaries

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))
- ★ Under law, the failure to comply with fiduciary obligations can cause liability—both personal and to the company

ERISA Fiduciary Responsibilities

- ★ 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

Plan Assets

- ★ A fiduciary must protect **plan assets** and ensure they are used for a proper purpose (benefits and direct expenses) and not engage in prohibited transactions
- ★ Medical Plan: Plan assets include all contributions made by participants and beneficiaries
 - > Even though there is a non-enforcement rule issued by the Department of Labor that, in general, premium amounts paid by active employees through a cafeteria plan do not need to be held in a trust—they are still considered plan assets

RECENT CASES

Transparency in Coverage Rule

- ✦ For the last 20 years, 401(k) and 403(b) plans have been the subject of putative class action lawsuits alleging excessive fees
- ✦ These lawsuits focus on fiduciary responsibilities with respect to vendor selection, fees and investment performance
- ✦ The transparency rules in the CAA and the ACA will change health care pricing forever
- ✦ As we anticipated, class action lawyers will use this information to bring lawsuits against health plans to claim that fiduciaries have not taken appropriate actions to rein in healthcare costs
- ✦ It will be critical for fiduciaries to conduct a rigorous RFP process for health plan services, monitor fees and to document that process

Lewandowski v. Johnson & Johnson

- ★ On February 5, 2024, plaintiff Ann Lewandowski filed a class action lawsuit against J&J and the fiduciaries of J&J's prescription drug benefits program ("J&J Defendants") in the District of New Jersey
- ★ Lewandowski's claims are premised on an alleged violation ERISA's duty of prudence under ERISA § 404(a)(1)(B)
- ★ At its highest level, she claims that the J&J Defendants acted imprudently by failing to manage drug costs of two J&J-sponsored health plans
- ★ The complaint claims that the J&J Defendants' alleged mismanagement has cost the Plans and participants millions of dollars in the form of higher drug costs, premiums, deductibles, co-payments, and co-insurance, and lower wages

Lewandowski v. Johnson & Johnson

- ✦ The complaint contains many allegations, including that the J&J Defendants did not meet their fiduciary obligations and:
 - > Failed to engage in a prudent and reasoned decision-making process before entering into the PBM contract that included such high-costs
 - J&J could have used its bargaining power to get better terms
 - Did not include a pass-through PBM in the RFP process
 - > Failed to adequately negotiate favorable contract pricing terms
 - > Failed to obtain the ERISA § 408(b)(2) disclosures for its broker, as a way to if broker had a conflict of interest

Lewandowski v. Johnson & Johnson

- ★ The complaint spends a lot of time on what should be considered the “benchmark” for determining the appropriate prices for drugs
- ★ In the 401(k) fee cases, some courts have required that a 401(k) plan participant alleging excessive investment management or recordkeeping fees must assert a “meaningful benchmark” in order to survive a motion to dismiss
- ★ Lewandowski tries to do this by referring to the NADAC and the cash price for the uninsured

Lewandowski v. Johnson & Johnson

- ✦ Some commentators have focused on the fact that the J&J plans were funded with VEBAs
 - While this makes it clear what are “plan assets”, it may not be a key factor in this case
- ✦ What may be the biggest challenge to Lewandowski is standing
- ✦ Plaintiffs must establish that they have sustained a concrete injury to bring a lawsuit in federal court
- ✦ In a recent case titled *Knudsen v. MetLife* (2023), a district court in New Jersey dismissed the plaintiffs’ claims on grounds that the plaintiffs lacked Constitutional standing because they had received all benefits owed to them
- ✦ In that case, participants paid approximately 30% of the health plan costs and the employer paid 70% of the health plan costs

Knudsen v. MetLife

- ✦ Between 2016 and 2021, the Plan earned approximately \$65 million in drug rebates, which Plaintiffs allege Defendant wrongfully paid to itself for its own benefit
- ✦ The Plaintiffs claimed that had the drug rebates been properly allocated, Defendant "may have reduced co-pays and co-insurance for pharmaceutical benefits" and "may have distributed rebates to participants in proportion to their contributions to the Plan."
- ✦ The court stated that (1) plaintiffs did not allege that they were denied any promised health benefits or had to pay higher costs than those set forth in the Plan's governing documents; and (2) plaintiffs were not entitled to the drug rebates under the Plan's governing documents

Knudsen v. MetLife

- ✦ The court stated that to determine whether Plaintiffs have alleged individual injury, the Court must examine whether the Plan is a type of defined benefit plan or a defined contribution plan
 - > This is based on the US Supreme Court case *Thole v. U. S. Bank*, in which the Court stated, at a high-level, that defined benefit plan participants who have not seen their own benefit payments reduced or otherwise altered cannot sue the plan fiduciary for failing to live up to ERISA's fiduciary duties
 - > The Supreme Court drew a distinction between defined benefit plans and defined contribution plans in such matters, noting that defined contribution plan participants can prove standing in fiduciary breach lawsuits far more often because their benefit value directly fluctuates along with the financial condition of the plan, whereas it is the plan sponsor that carries the risk in defined benefit plan

Knudsen v. MetLife

- ★ The court stated that even if Plaintiffs were correct that the drug rebates should have been allocated as Plan assets, plan participants had no legal right to the general pool of Plan assets just like the plaintiffs in *Thole* were not entitled to any additional money in the retirement plan beyond the monthly payments that they were "legally and contractually" entitled to receive
- ★ In addition, the court stated that the Plaintiffs' claim that absent fiduciary mismanagement, Defendant "may" have reduced co-pays and co-insurance or that Plan participants "may" have received a proportionate distribution of rebates, was also speculative and conclusory

Lewandowski v. Johnson & Johnson

- ✦ There are a few differences in this case from the *Knudsen* case
 - > First, a main allegation in the J&J case is that the plaintiffs overpaid in the deductible and coinsurance due to the plan fiduciaries breaches
 - This is different than not returning rebates to plan participants—especially when the plan document and SPD are clear that rebate amounts will be retained by the employer
 - > Second, there is an allegation of a prohibited transaction, in that the J&J Defendants did not follow the requirements of ERISA § 408(b)(2)

Prudent Process

- ✦ In a recent Second Circuit case, Goldman Sachs, an ERISA plan fiduciary of its 401(k) Plan, successfully defended a class action lawsuit alleging breach of its ERISA fiduciary duties
- ✦ The plaintiffs alleged that Goldman Sachs and its 401(k) Committee ("Goldman") mismanaged the Plan by giving preferential treatment to proprietary funds managed by Goldman Sachs Asset Management
- ✦ The Second Circuit affirmed the lower court's grant of summary judgment in favor of Goldman Sachs

Prudent Process

- ★ The Second Circuit focused on the robust process used by Goldman—once again emphasizing that having a diligent and robust process is a cornerstone of ERISA
- ★ Goldman:
 - > employed a robust process to manage potential conflicts of interest,
 - > participated in fiduciary training sessions,
 - > retained an investment consultant to act as an independent advisor and provide unbiased advice, and
 - > took other similar types of actions, all of which were documented

ACTION ITEMS

Some Suggested Action Items

- Conduct RFPs for service providers (including PBMs) at a regular interval (every 3-5 years);
- Work with experts to negotiate service provider contracts, including PBM contracts;
- Use the newly available information from the CAA and the ACA to conduct cost comparisons;
- Identify consultants and brokers subject to the new ERISA § 408(b)(2) rules for health plans;
 - Assign internal responsibility for soliciting the disclosures and evaluating compensation;
 - Develop a process to evaluate if the disclosure provides sufficient information to understand the amount of direct and indirect compensation received by the consultants and brokers and determine whether the indirect compensation creates a conflict of interest;
- Document the decision-making process.

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