Bringing "Transparent Thinking" to PBM Management

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Topics For Today

- What is a PBM?
- Who are the parties to a PBM contract?
- Why do PBMs have so much power?
- How do PBMs make money?
- Contract terms—the need for solid terms in a contract
- A push for transparency
- Policy news
- A real life example: PBGH's Waste-free formulary study

What is a PBM?

- We generally think of the Pharmacy Benefit Management companies (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 discounts
- Employers often do not understand the terms of the contract or the amount of direct/indirect compensation paid to the PBMs
  - Employers have supported the current system to "avoid" paying the ASO fees—this makes it hard to determine if the vendor is receiving reasonable compensation for its services

What is a PBM?

- Employers rely on the PBM to create savings for the plan and the plan participants
- The savings have mostly not materialized for the employers—employers pay far too much prescription drugs and have become too reliant on rebate checks
- PBMs have a massive 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, the terms of the contract and things to push on Congress/the White House to change

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

- It is estimated that employer-sponsored group health plans ("GHPs") cover approximately 156 million Americans—more than Medicare and Medicaid combined (Kaiser Family Foundation, 2017)
- Some experts estimate that as much as 20% of the total cost of GHP coverage is spent on those plans' prescription drug benefits

PBMs—A Powerful Group

- Three PBMs control close to 80% of the GHP market: (1) Express Scripts, (2) CVS Caremark and (3) OptumRx
- Express Scripts reported a profit of $3.4 billion in 2016, up 34% from 2015. OptumRx reported an operating profit of $2.7 billion in 2016, up from $1.7 billion the year before. (LA Times)
  - CVS does not separately report its PBM financials
- PBM profits have increased year-over-year and by some estimates, have grown over 600% since 2003 (David Blato, *The Right Prescription for Reforming PBMs in California, 2017)*

PBMs—A Powerful Group

- Since 1987, total spending on prescription drugs in the U.S has increased over 1000% percent, from $26.8 BILLION to $297.6 BILLION (Statista, Inc.)
- Overall price inflation in the U.S. only grew 125.9% in the same period
- The focus of this presentation is not to hate the PBMs, but to understand the industry and push for TRANSPARENCY. The employer-sponsor should have a better understanding of the amount of compensation it pays to a PBM and if that is reasonable compensation for the services provided to the plan

PBMs—A Powerful Group

- An entity that does not do the research for the drugs or manufacture the drugs—has massive growth each year
- Where does it get its profits?
- How does the employer 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 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, which supply and set the wholesale rates at which pharmacies obtains 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 pay the "full cost" until the deductible is met

Where the Money is Made

- The main 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 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 at the price of AWP less 15%, but the PBM separately offers the GHP a smaller discount of AWP less 12%
  - The 3% differential is referred to as the "spread" which the PBM retains as profits from the transaction
  - The spread can be as much as $65 for one prescription (Benefits Pro, *Exposing the PBMs' Spread Compensation)*
  - 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. Sometimes this means eliminating a less expensive, comparable medication from the 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, 2016)
  - 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
  - One of the main drivers of whether a drug is on a formulary is the amount of the rebate –not if it is the best "net" priced drug or the most suitable drug for the injury or illness

Rebates

- An employer may think it need not worry about this structure since it receives 90%+ of the rebates
  - Consider: (1) are there other fees paid to the PBM by the manufacturer that are relabeled and therefore are no longer considered a "rebate" (2) should a lower cost drug be on the formulary, (3) what is the spread compensation for the drug that was chosen for the formulary, and (4) does the employer even have access to the right information to make these decisions?

Capturing Coupon Amounts

- Many GHPs have large deductibles
- Pharmaceutical manufacturers offer copayment offset programs (also called copay cards or coupons) that cover a participant's out-of-pocket costs and/or deductible for a brand-name specialty drug
- The idea is for the manufacturer to assist the participant with the cost of the drug while he/she is in the deductible
  - It can create brand loyalty and discourage use of generics or lower cost alternatives
- Example: Amy takes Humira for arthritis. It can cost tens of thousands of dollars a year, but Amy has been assisted with discount coupons from the drug's manufacturer. The coupons apply to Amy's $2,000 deductible.
  - Amy no longer has the incentive to consider whether there are lower cost options
  - Amy is no longer sharing in healthcare costs as was the original intent of the plan design
  - Amy's deductible is paid by the manufacturer but Amy's co-workers with high hospital or doctor costs must pay their full deductible
- Some GHPs changed this practice by introducing "copay accumulators" which means that coupons don't count toward a patient's deductibles

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 have a solid understanding of contract terms and pricing
  - If the employer does not have someone in-house who can do this, find someone who understands the terms. Do not just rely on a general consultant

Contract Terms

- How is the term "rebate" defined in the contract? Example of a definition recently seen 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."

Contract Terms—Rebate

- What if the PBM contract with a drug manufacturer gives rebates another name — like administrative fees or health management fees or grants?
  - the PBM will arguably eliminate its obligation to pass on the rebate
- What if the rebate is paid on a basis that is not 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 attributable to any particular client

Contract Terms—Rebates

- Create a new definition for the contract—such as financial payments or financial incentives
- Include a list of all types of payments that could be received by the PBM and start the list with "including, but not limited to…"

Contract Terms—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."

Contract Terms—Brand and Generic

- What does that mean???
- Under the above definition, the PBM is likely to categorize all single-source generics as brands
- How audit against this definition? What is the standard?

Contract Terms—Brand and Generic

- Many PBM contracts allow the PBM to classify drugs for one purpose in one way, and for another purpose in another way
  - This is done intentionally so that the PBM has discretion on how it defines drugs and not being locked in on one characterization of a drug in order to maximize profits
- 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

Contract Terms—Co-Pays

- Another example of pricing spread is when drug costs are lower than patient copays
- PBMs often force pharmacies into contracts where they have to sell drugs at the contracted rates, and then the PBM "claws back" the excess copay for themselves
  - EXAMPLE: Co-pay is $30 for xxx drug. But xxx drug costs $20. Pharmacy is required to charge the $30. PBM will later recoup the $10.
- The contract with the PBM should address this issue

Contract Terms—Transparency

- Require the PBM to provide all documents and data related in any way to any financial benefits, including but not limited to all contracts with manufacturers and other third parties, all documents reflecting third party payments to the PBM, etc...
- Require a PBM to provide the employer with the information necessary to verify the accuracy of calculations—do not allow the PBM to hold back some information as "confidential"
- Ensure that the PBM invoices the plan with the PBM's actual reimbursement to the pharmacy—in other words, the invoicing at least shows what the PBM pays the pharmacy versus charges the plan

Contract Terms—Scope of Services

- Consider all of the services being provided by the PBM
- 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 likely has 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, etc.. is worth consideration
  - This converts the PBM to an administrator role

Contract Terms—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
- 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…
- Blackout Dates: The PBM may want to allow for only certain window periods for audits. Do not accept unreasonable limits.

Contract Terms—RFP

- To get these terms, provide a sample contract 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
- Some PBMs will drop out of the RFP process, rather than be transparent or agree to abide by definitions that cannot be manipulated or changed

Contract 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 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 are likely a better deal for the employer albeit a counter-intuitive notion

Actions for Plan Sponsors in Contract Process

- Use the RFP process to demand strict terms/transparency
- Understand PBM contracts and how a PBM receives direct and indirect compensation
- Specifically define terms in the contract
- Lock down audit rights
- Find help from experts—do not use a general benefits consultant—this is tricky stuff!
  - The spread compensation and other indirect compensation has been an issue for years. If your consultant has not flagged this for you during pervious negotiations, it may not be the right consultant to negotiate a PBM contract

Push for Transparency

- Plan sponsors should push Congress and the White House for more transparency
- Congress has passed laws that allow for the Department of Labor ("DOL") and the Department of Health and Human Services ("HHS") to issue regulations that would require transparency—but no regulations have been issued for ERISA-covered plans

Push for Transparency

- A bit of history…The ERISA Advisory Council advises the DOL on matters related to employer-sponsored group health plans. In 2014, it examined if PBMs should be required to disclose fees and compensation to plan sponsors so that the health plans could determine if the ERISA prohibited transaction rules were violated due to the PBM being paid more than reasonable compensation for its services
- The answer was yes—regulations were needed for the health plans
  - Regulations were issued for retirement plans under ERISA Section 408(b)(2), which changed the amounts vendors charged to those plans

Push for Transparency

- While the DOL wanted to issue regulations for health plans, the Federal Trade Commission ("FTC") blocked the issuance of such regulations because:
  - Mandatory disclosure would hinder the ability of plans to negotiate an efficient level of disclosure
    - (This does not make sense)
  - If the information was publicly revealed about the discounts negotiated with the PBMs, disclosure would result in collusion with the pharmaceutical manufacturers
    - (This seems unlikely)

Push for Transparency

- One FTC Commissioner dissented and stated that the Agency had not done a true study on the issue since 2005—long before the mass consolidation of the PBM industry
- The transparency rules for Medicare are far superior to those for ERISA plans—such as being required to disclose the aggregate amounts rebates and discounts, the amount of the spread compensation, etc…
  - While those rules are not without faults, they are a place to start

Action for the DOL

- Employers should send letters to the DOL and to Congress requesting action. Examples of things that could be done by the DOL (without Congressional action) are listed on the next slides

Action for the DOL

- ERISA Section 406 prohibits the furnishing of services between a plan and a party in interest—considering it a prohibited transaction, unless an exemption is met
  - A party in interest includes any entity providing services to the plan (which would include a PBM)
- ERISA Section 408(b)(2) provides an exemption from ERISA Section 406 so long as the contract is reasonable, the services are necessary and no more than reasonable compensation is paid to the party in interest

Action for the DOL

- In 2012, the DOL issued final regulations under ERISA Section 408(b)(2) requiring the providers of services to disclose all direct and indirect compensation received—but those regulations only apply to retirement plans
  - The regulations specifically reserve for future consideration the disclosure of direct and indirect compensation for health plans
- Employers should demand that ERISA Section 408(b)(2) regulations be issued for health plans
- Transparency is needed. Employers must have this information to understand if reasonable compensation is being paid to the PBMs

Some Recent Cases

- In 2017, CVS Health, Express Scripts, and Prime Therapeutics were sued over their EpiPen pricing practices. The claim was that the PBMs did not effectively negotiate for lower EpiPen prices but instead negotiated for "increasingly large rebates" from Mylan. The plantiffs allege that this benefited the PBMs and drove EpiPen prices up by more than 600% over the past decade.
- Plaintiffs' asserted several causes of action including: (1) violating ERISA § 406 by engaging in prohibited transactions and (2) violating ERISA § 404 by breaching fiduciary duties of loyalty and prudence
- The case is moving forward in the courts.

Some Recent Cases

- As discussed earlier, some participants make co-payments under their plan that exceed the price of the prescription drug and then the PBMs clawback from the pharmacies the excess amounts paid
- Lawsuits have been filed regarding this practice, asserting that the PBMs have breached their fiduciary duty under ERISA
- In two recent cases, the courts have concluded that the fiduciary duty analysis turns on whether the defendants exercised any discretionary authority or control in creating and implementing the alleged clawbacks (*Negron v. Cigna Health & Life Ins.* and *In re UnitedHealth Grp. PBM Litig.*)
- The fiduciary claim was dismissed in the UnitedHealth case, but that same claim survived a motion to dismiss in the Negron case

Some Recent Cases

- The concept in these cases is that the PBMs are acting as a fiduciary
- For a PBM to be an ERISA fiduciary, it would need to be determined that it had discretionary control over ERISA plan assets. This could occur if participants paid part of the cost of the plan (which is often the case) and that the PBM ultimately decided the amount that the plan paid for drugs.
- In the past, the courts have reviewed the services agreement with the PBM to determine whether the PBM is a fiduciary. Many courts have determined that the employer-sponsor agrees to a set price for the drugs and the PBM just follows the terms of the contract—so the PBM did not have discretionary control over plan assets.
- In addition, many PBM contracts specifically state that the PBM is not a fiduciary and all drug pricing and formularies are determined by the employer
  - This is not reality, but the PBMs have won on this argument, many times!

Legislation

- In October of 2018, the Patient Right to Know Drug Prices Act became law
- It prohibits gag clauses, which are provisions in PBM contracts that prohibit pharmacists from telling customers they could save money by paying cash out-of-pocket instead of using their insurance

State Legislation

- Many states have passed laws regarding PBM fiduciary status, drug cost transparency and disclosure, as well as increased regulation and licensure requirements
- The PBMs will fight these laws on the basis of ERISA preemption
- Action must be taken by the DOL. Write your federal representatives and demand that transparency rules be issued.

A "real life" example
Common Formulary Feasibility Study

The COMMONWEALTH FUND

Waste-Free Formulary Feasibility Study

Is there enough waste to justify this as a collaborative effort across purchasers (and therefore across PBM contracts?)	What would it take for physicians to prescribe to a common waste free formulary?	What are the obstacles to purchaser adoption? Will they make changes?
Integrity Pharmaceutical Advisors, LLC	CAPG · California Academy of Family Physicians · CMA — *Medical groups, IPAs, doctors!*	
Use employer data to unpack pricing, model different formulary choices, estimate savings	Use partnerships with trusted provider associations to engage physicians. Use focus groups to fully understand all issues.	Work with employers to understand and address obstacles presented by PBMs, consultants, and concerns about member disruption.

Findings

1. Yes-there is waste, should be addressed although a "common" formulary is not the approach
2. Yes-physicians will adjust prescribing patterns if they have relevant information
3. Yes-employers WILL use this information to adjust formularies, albeit to varying degrees

Findings-Yes, there is waste

- 15 Data Donors submitted data (4 ESI, 8 CVS, 3 Optum)
- 2,543,907 claims evaluated of which 6% were wasteful, consisting of 868 different drugs
- Data was limited, assumptions were conservative
- No controversial drugs (.01% specialty)
- Only considered if excluding the drug saved > 25%
- Savings had to apply across formularies, i.e. specific formulary "deals" were excluded
- Case study-based assumptions about patients' behavior
- Savings were 11% less than comparative case studies due to conservative assumptions
- Estimated savings of this data set was $63.3 million
- Represented 2.8% to 24% of total PBM spend (for 9 data donors for whom we knew total spend. 10-24% for 7 of the 9. Two of the 9 had already begun managing their formulary.

Start with these 8 culprits…ask your PBM and/or consultant what you spent on these, and why

Drug	Scripts	Savings
MetFORMIN HCl ER (MOD & OSM)	1,049	$ 3,472,137
Dexilant	3,170	$ 2,282,770
Duexis	428	$ 1,638,284
Mometasone Furoate	3,151	$ 1,323,248
Absorica	512	$ 1,279,028
Solodyn	622	$ 1,265,560
Esomeprazole Magnesium	4,201	$ 1,017,398
Jublia	645	$ 980,287

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