PLAN
SPONSOR
NEWS

June 2020

FRIER LEVITT
ATTORNEYS AT LAW

Helping large employers, union groups and self-insured companies understand their drug benefit design.

In this issue:

The Impact of COVID-19 on PBM Contracts

Authored by Dae Y. Lee, Pharm.D., Esq. CPBS and Jesse C. Dresser, Esq.

The novel Coronavirus ("COVID-19") pandemic has impacted every aspect of our personal and business lives, including the healthcare industry. While healthcare providers put their health and safety on the line to combat the pandemic, Pharmacy Benefit Managers ("PBMs") may be taking advantage of Plan Sponsors.

Plan Sponsors, ranging from self-insured employers to government entities, have taken steps to relax requirements so that patients have access to healthcare and life saving drugs. However, some PBMs have taken the opportunity to syphon money out of Plan Sponsors, at the expense of both Plans and patients. We will discuss three areas of concern for Plan Sponsors during COVID-19.

Price Guaranty Provision. PBM contracts often contain force majeure provisions that would allow PBMs to escape price guaranty provisions that have been negotiated by and between Plan Sponsors and PBMs. While price guarantees favor Plans, many force majeure provision potentially relieve PBMs of their contractual price guaranty obligations because of circumstances that are out of their control (e.g., COVID-19). In other words, PBMs, free of price guaranty provisions, can increase their revenue exponentially at the expense of Plan Sponsors and patients. More specifically, PBMs can create a larger spread, i.e., the difference between the amount of fees charged to Plan Sponsors for prescription drug claims and the reimbursement PBMs pay for such drugs to pharmacies in the PBM network. Notably concerning, PBMs have cut reimbursements for certain medications including anti-depressants. Express Scripts, Inc. ("ESI") reported that antidepressants, anti-anxiety and anti-insomnia drugs increased by 21% between February 16 and March 1. Yet, ESI cut reimbursement for these drugs needed by patients now more than ever. In addition, due to the force majeure provisions, PBMs can deviate from rebate guarantees and pocket more revenue for themselves. Plan sponsors need competent healthcare counsel to review these agreements and design a game plan to protect their interests.

Days Supply Limits. Second, temporary suspension on quantity and days supply limits under 90 days could become a major issue for Plan Sponsors. The Centers for Medicare and Medicaid Services ("CMS") has issued guidelines waiving certain requirements for Plan Sponsors in order to reduce patient encounters with their pharmacies and deter further spreading of the COVID-19. One of CMS's actions was a waiver of restriction on quantity and days supply. Concurrently, CVS Caremark ("Caremark") has announced that it is working with PBM clients to waive early refill limits on 30-day prescription maintenance medications. Caremark has also announced that it is waiving the policy of its affiliated pharmacy, CVS Pharmacy, to charge for home delivery of prescription medications, and that it is actively working with clients who do not offer 90-day supply benefits to waive early refill limits on 30-day prescription maintenance medications. Many PBMs have their own mail-order pharmacy. Now, without the 90-day supply restriction, PBMs are using this opportunity to push 90-day fills to the PBM's wholly owned mail order pharmacies. In fact, some PBMs are projecting increases in members receiving 90-day mail-order prescriptions to be upwards of 20% even in voluntary mail programs. Notably, PBM-owned or affiliated mail order pharmacies have

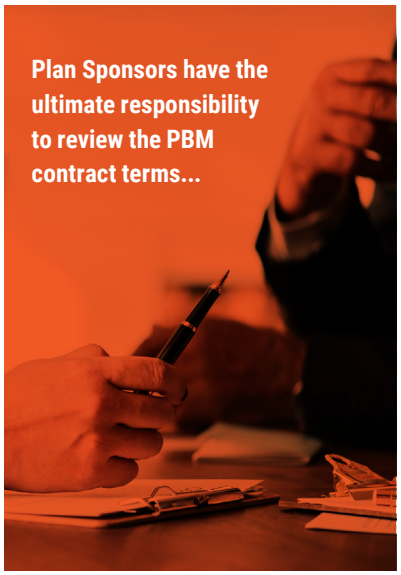
been placed under scrutiny for putting their profits in front of patient care. For the patients, it certainly limits patient access but also patients have reported instances where PBMs denied their prescriptions written or authorized by the patients' physicians and where the PBM-owned or affiliated mail order pharmacies have not mailed their prescriptions on time. For the Plan Sponsors, drug spending will inevitably increase because PBMs have often negotiated better price guarantees for their own mail-order pharmacies that fill prescriptions for the 90-day supply, in comparison to drugs filled by independent pharmacies in the network. That being said, Plan Sponsors should anticipate to see a disruption in their usual monthly payments for pharmacy benefits.

Refill Too Soon. Lastly, the waiver of refill-too-soon restriction could be another source of revenue for PBMs at the expense of Plan Sponsors. In the CMS guidelines mentioned above, CMS required Medicare Part D Plan Sponsors to relax their "refill-too-soon" restrictions. Likewise, Caremark has announced that it is working with commercial PBM clients to waive early refill limits on 30-day prescription maintenance medication. Coupled with the relaxed restriction, PBMs' patient steering to the their wholly owned or affiliated pharmacies will increase Plan Sponsors' drug spending. It is well documented that PBMs have negotiated better pricing guarantees for their own pharmacies. Therefore, waiver of refill-too-soon restriction will encourage PBMs to steer patients and troll prescriptions to their own or affiliated pharmacies at the expense of Plan Sponsors. Plan Sponsors should carefully comb through the current contracts as well as applicable laws that would prevent PBMs' from engaging in patient steering.

In summary, policies and guidelines issued by government agencies as well as relaxed guidelines set forth by PBMs amid COVID-19 pandemic will have the potential to affect pricing, costs to Plan Sponsors, and utilization trends. Plan Sponsors should consult with industry experts to navigate complex web of PBMs revenue schemes and tactics. ■

Key Items in Pharmacy Benefit Manager Contracts

Authored by Dae Y. Lee, Pharm.D., Esq., CPBS and Jonathan E. Levitt, Esq.



Contracting with Pharmacy Benefit Managers ("PBMs") is a daunting task and one that Plan Sponsors should not delegate and entrust to non-fiduciary brokers or consultants. Some benefit brokers put their personal interests above their clients and receive, unbeknownst to Plan Sponsors, substantial financial incentives from PBMs. Plan Sponsors have the ultimate responsibility to review the PBM contract terms and ensure that there are no vague contract terms that would hinder Plan Sponsors' ability to monitor PBM performance. PBMs use loose terms to create hidden revenue streams. Frier Levitt has identified several pitfalls in PBM contracts, some of which are listed below.

Limitation on Auditing Rights. Plan Sponsors must audit PBMs to effectuate cost-containment strategies and to optimize services provided to the beneficiaries. However, many PBM contracts contain contract language substantially limiting full audit rights to Plan Sponsors. PBMs will also include certain conditions that Plan Sponsors need to establish before conducting a PBM audit. For example, with respect to audits regarding manufacturer rebates that PBM are supposed to pass on to Plan Sponsors, PBMs conceal secretive relationships they have entered into with Rebate Aggregators. Frier Levitt has reviewed PBM contracts where Plan Sponsors are prohibited from conducting audits on drug manufacturer rebates. It is imperative that Plan Sponsors have full audit rights to all PBM network pharmacy contracts, claims data, manufacturer rebate and administrative fee contracts, mail service purchasing invoices, clinical coverage criteria, and formulary decision-making records. Preserving these rights requires having competent healthcare counsel to negotiate Plan Sponsor agreements.

Rebate Guarantee. Possibly the most significant opportunity for PBM abuse of Plan Sponsors arises in the context of manufacturer rebate relationships. The key is in the contract wording. A "full passthrough" of rebates does not necessarily mean all of the revenue that the PBMs are receiving from the manufacturer are passed on to Plan Sponsors. As we explained here and above, PBMs have weaved in contractual terms that would prevent Plan Sponsors from uncovering the true amount of manufacturer rebates procured and retained by PBMs. Plan Sponsors should have fully transparent relationship with PBMs but such relationship can only be created through a carefully crafted contract. The contract should list out all the types of revenue and have an agreement upfront for both parties as to the amount of rebates – always try to negotiate a fixed dollar rebate and do not allow PBMs, to pay a rebate per formulary script – that will be passed onto Plan Sponsors and that will be retained by PBMs. Importantly, Plan Sponsors should demand PBMs to produce list of sub-contractors or Rebate Aggregators that PBMs intend to use for rebate administration and their underlying

agreements. Plan Sponsors should have the final authority to agree to have PBMs contract out the rebate administration function.

Differential pricing. Another key component of the Plan Sponsor contract with PBMs relates to differential pricing. Most PBMs employ a traditional pricing approach known as spread pricing or differential pricing, meaning that the PBM negotiates to pay pharmacies in the network aggressively low reimbursement rates for drugs and, in turn, invoices the PBM customer, the Plan Sponsors, at higher contracted rates. PBMs profit from the spread between what the Plans pay the PBM and what the PBM in turn, pays the pharmacy. In order to take control over the spread pricing scheme, Plan Sponsors must require PBMs to identify and use either the lowest pricing source for each drug or the pricing source that represents, on average, the lowest Average Wholesale Price ("AWP") prices. PBMs use two sets of Maximum Allowable Cost ("MAC") drug pricing lists for generics. One MAC pricing list is paid to the pharmacy, and a different MAC pricing list for the same generic drugs is charged to the Plan Sponsor. The PBM enjoys the spread between these two sets of pricing lists. Plan Sponsors should demand PBMs to use one comprehensive MAC list and also demand transparency in pricing.

As prescription-drug costs become an ever-increasing portion of Plan Sponsor's healthcare spend, Plans should seek healthcare counsel to negotiate PBM contracts and demand full transparency from PBMs. ■

Plan Sponsors are far too credulous of Pharmacy Benefit Managers ("PBMs") when it comes to understanding drug manufacturer rebate revenue. Rebate administration is one of the main services that PBMs offer to Governmental entities, self-funded employers, insurers, and managed healthcare organizations (collectively, "Plan Sponsors"). PBMs receive two types of rebates: Manufacturer Rebates and Pharmacy Rebates. "Manufacturer Rebates" are cash payments made by pharmaceutical manufacturers to PBMs that are theoretically designed to act as drug discounts. "Pharmacy Rebates" are point-of-sale fees or post-sale chargebacks (e.g., audit recoupment) that PBMs retain from their member pharmacies. Unfortunately, rebates became a lucrative revenue source for non-transparent PBMs at the expense of Plan Sponsors, manufacturers, patients, pharmacies and taxpayers.

Understand the Truth About PBMs and Manufacturer Rebate Revenue

Authored by Dae Y. Lee, Pharm.D., Esq., CPBS and Jonathan E. Levitt, Esq.

PBMs market themselves as "transparent" and purport to "pass through" all rebates to Plan Sponsors. However, recent litigation has brought that into question. We have seen alarming instances where PBMs secretly use little-known Rebate Aggregators that are often PBM-owned or affiliated in the Manufacturer Rebates arena. Plan Sponsors hire PBMs to administer and manage pharmacy benefits for their members and beneficiaries. In turn, PBMs negotiate Manufacturer Rebates with drug companies on brand-name drugs in exchange for placing a particular drug on a PBMs' drug formulary. If that sounds like a questionable quid pro quo arrangement, that is correct. Unbeknownst to Plan Sponsors, PBMs delegate collection of Manufacturer Rebates to Rebate Aggregators who keep a large portion of the Manufacturer Rebates without telling Plan Sponsors. In fact, it is extremely difficult to grasp the true rebate dollars collected by PBMs and Rebate Aggregators, in part because publicly traded PBMs carefully guard this revenue and do not report in their quarterly SEC filings. This is even true for Plan Sponsors in the public sector such as State Medicaid agencies and municipalities.

PBMs continue rebate schemes even in the federal payor space. Medicare Part D Sponsors are required to submit **Direct and Indirect Remuneration ("DIR")** reports to CMS disclosing the total amount of rebates, inclusive of Manufacturer Rebates and Pharmacy Rebates, retained by PBMs regardless of whether such rebates were passed to Part D Sponsors. Sponsors are legally obligated to populate the DIR fee data into the CMS reports. Oftentimes, Sponsors receive this date from PBMs, who have performed the rebate collection on behalf of the Part D Sponsors. PBMs and Rebate Aggregators are mandated to provide the following information to Part D Sponsors, who in turn provide the same to CMS:

1) The total number of prescriptions that were dispensed.
2) The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies.
3) The percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy,

chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the Part D sponsor or PBM under the contract.

4) The aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees as defined in § 423.501) that the PBM negotiates that are attributable to patient utilization under the plan.

5) The aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.

6) The aggregate amount of the difference between the sum the Part D sponsor pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies.[1]

Using the DIR reports, CMS will ultimately conduct the reconciliation of the risk corridor, reinsurance, coverage gap discount program, and low-income cost-sharing subsidy under Medicare Part D. Simply put, in the event that PBMs and Rebate Aggregators secretly retain significant amounts of Manufacturer Rebates, Part D Sponsors will likely bear financial responsibility to CMS. Even with the foregoing, the rebate arena is highly secretive and current laws do not necessarily require tracking and disclosure of rebates. Competent healthcare litigation counsel can help uncover these hidden dollar arrangements, bringing relief to Plans.

One example of a rebate scheme is well documented in Broward County's Audit Report over OptumRx[2]. It revealed several alarming practices, *among other things*, a complex web of contracts (OptumRx contracted with the Coalition for Advanced Pharmacy Services ("CAPS"), which in turn contacted with Express Scripts, Inc. ("ESI")) to maximize rebate retention for the benefit of OptumRx and to the detriment of the Plan. OptumRx purported that it paid Broward County all rebate funds it received, through CAPS, from the drug manufacturers. However, the rebate funds received by Broward County **do not account** for the funds retained by CAPS. Ironically, OptumRx and CAPS are both subsidiaries of UnitedHealth Group. All Plan Sponsors should take the opportunity to exercise their right to audit PBMs to ensure this scheme is not depriving Plans of pressure resources.

Another example of rebate scheme is described in a report issued by Office of the Legislative Auditor General for the State of Utah, which revealed troubling findings regarding Manufacturer Rebates. The auditor examined the relationship between the State's Public Employees' Health Plan ("PEHP") and its PBM, ESI. In the report, the Auditor noted, *among other things*, that the average drug prices increased 8 percent from 2016 to 2017 but rebates retained by ESI were not keeping pace with drug prices. To make matters worse, ESI did not allow PEHP access to claim-level rebate information through regular reporting or auditing. The PEHP was prohibited from verifying the total rebates that ESI procured on behalf of PEHP. Plan Sponsors are cautioned to negotiate robust auditing provisions in PBM contracts to prevent such schemes.

Another example of a self-serving rebate arrangement designed by a PBM is evident in a whistleblower complaint initiated by a former employee of Novartis Pharmaceuticals Corporation's former employee. In the lawsuit[3], the complaint alleges that Novartis directed the relator "to carry out the company's practice of swapping commercial rebates and other incentives in return for" Medicare Part D business with ESI. Furthermore, the complaint notes that, as a result of the illicit swapping of rebates, "ESI's commercial plans received a 10% rebate rate, while ESI's Part D plans received the minimal 6.375% rebate rate." Again, tight Plan Sponsor contracts with PBMs can prevent the siphoning of rebate revenue.

It is not hard to imagine that rebate abuse is more prevalent in the private sector since there are no Medicare and Medicaid reporting requirements unless such disclosure is contractually required under the PBM-Plan Sponsor agreement. What's worse is that PBMs play wordsmithing games in Plan Sponsor contracting. Plan Sponsors get zero information directly from Rebate Aggregators, Plan Sponsors have no "direct contractual privity" with Rebate Aggregators, and in fact Plan Sponsors seldom know of the existence of these secretive entities. PBMs use complex contractual verbiage to limit the scope and extent of rebate sharing in order to maximize their profit. Therefore, unless demanded by and through strong contractual terms, PBMs are not obligated to disclose the rebates they receive from rebate aggregators, even those that the PBM wholly owns. Moreover, depending on the contractual terms, Plan Sponsors may not have the right to conduct rebate audit on PBMs. It is critical to have a carefully drafted contract, reviewed by experienced healthcare counsel.

The current laws do not require sufficient disclosure by PBMs of their rebate aggregation and do not require that rebates take into account patient care. The current administration withdrew a Notice of Proposed Rule Making (NPRM) in 2019 that would have altered the drug marketplace. The NPRM sought to eliminate the "Safe Harbor" that permits PBMs to legally extract billions of dollars in Manufacturer Rebates with little or no transparency. Also, the proposed rule would have encouraged higher utilization of low-cost generic and biosimilar drugs, as PBMs would no longer have an incentive to favor brand-name drugs in their formulary. With the Rebate Safe Harbor intact, PBMs will continue to generate massive revenue through Manufacturer Rebates. The cancellation of the proposed rebate rule will continue to bring financial harm to Plan Sponsors, independent pharmacies, patients, and taxpayers.

Plan Sponsors should consult with industry experts who have an in-depth knowledge of the PBM industry and who understand PBMs' lingo to uncover self-serving rebate arrangement. Otherwise, Plan Sponsors will end up losing precious resources as victims of PBMs' revenue schemes. ■

[1] *42 CFR 423.514(d) (emphasis added).*

[2] *Audit of Pharmacy Benefit Management Services Agreement, Office of the County Auditor. https://www.broward.org/Auditor/Reports/Documents/2017_1212%20Agenda%20Review%20of%20Pharmacy%20Benefit%20Management%20Services%20by%20StoneBridge/2017_1212%20Exh1_OptumRx.pdf*

[3] *United States of America ex rel. Joseph Perri v. Novartis Pharmaceuticals Corp. et al., case number 2:15-cv-06547, in the U.S. District Court for the District of New Jersey.*

The purpose of "Reverse Auction Procedure" is to drive Pharmacy Benefit Managers ("PBMs") to submit highly competitive bids to governmental entities, self-funded employers, insurers, and managed healthcare organizations (collectively, "Plan Sponsors"). The reverse auction procedure often yields more than 15% savings for Plan Sponsors' drug spending and allows Plan Sponsors to tailor a fiduciary PBM contract.

Embrace Reverse Auction Procedure and Protect Plan Dollars with Proper Contractual Tools

Authored by Dae Y. Lee, Pharm.D., Esq., CPBS

In September 2018, New Jersey Governor Phil Murphy announced that the State of New Jersey awarded the PBM contract to OptumRx and agreed to pay OptumRx $6.7 billion over three years to manage and administer pharmacy benefits for the State. Under New Jersey's reverse auction procedure, the State provided the formulary and other coverage details and the PBMs submitted corresponding bids. PBMs endured multiple phases of competitive bidding process to undercut each other. New Jersey claims the system – which covers approximately 800,000 public employees – would cut $1.6 billion from medication costs over three years without reducing benefits. Similarly, in New Hampshire, a wide-ranging group of businesses claim that they can save the state millions of dollars of prescription drug costs by adopting the New Jersey's reverse auction model.

However, the auction procedure is meaningless unless Plan Sponsors implement contractual tools that protect against PBM revenue tactics and schemes. Plan Sponsors should be armed with in-depth knowledge to prevent PBMs' abusive practices. In order to do so, Plan Sponsors must implement cost-containment strategies in their contracts with PBMs. Competent healthcare counsel is essential for this contract analysis.

This is because PBMs intentionally employ variations of Average Wholesale Price ("AWP") to create a mark-up or "spread" between the price charged to their clients, i.e., Plan Sponsors, and the drug reimbursement rate paid to pharmacies in the PBMs' networks. To appear as if they are offering a deal, PBMs often charge Plan Sponsors AWP less a specified discount even though this amount has no relationship to the reimbursement rate PBMs pay to network pharmacies. The egregious "spread pricing" schemes have been hurting independent pharmacies, virtually putting independent pharmacies out of business and eliminating competition. Notably concerning, Drug Channels reported that 95% of total U.S. equivalent prescription claims are handled by Top 6 PBMs: (1) Caremark; (2) Express Scripts; (3) OptumRx; (4) Humana; (5) MedImpact; and (6) Prime Therapeutics. Plan Sponsors should require PBMs to identify and use either the lowest pricing source for each drug or the pricing source that represents, on average, the lowest AWP prices. Furthermore, Plan Sponsors should contractually eliminate spread pricing to ensure that drug costs charged by PBMs match what PBMs pay their member pharmacies.

PBMs encourage the use of PBM-owned mail order services on the premise that this class of trade results in more cost-savings compared to drugs dispensed by retail pharmacies. This is not so. PBM-

owned/affiliated mail-order pharmacies are more prone to egregious pricing schemes, such as repackaging and repricing of medications, which ultimately result in higher margins for PBMs and a higher drug-spend for Plan Sponsors. Repackaging typically occurs when PBMs-affiliated/owned pharmacies turn single purchase of medications into different quantities and configurations than how they were originally supplied by the drug manufacturer, and ultimately set inflated AWPs. PBMs can assert their influence over prescribing physicians to generate more non-preferred brand-name medications versus cheaper generics, and steer patients to their mail-order pharmacies. Therefore, Plan Sponsors should refrain from contracting with PBMs that own a mail-order or specialty pharmacy unless the contract is a fiduciary contract. Alternatively, Plans Should contractually permit independent pharmacies to participate in the pharmacy network.

Manufacturer rebates have become a significant portion of PBMs' overall revenue and profitability. Manufacturer rebates are presumptively designed to provide another layer of cost-containment for Plan Sponsors. However, manufacturer drug rebates have morphed into a prime area of PBM abuse. PBMs create and implement their own "formulary" to maximize rebate revenues from manufacturers. PBMs do not pass through all of these rebates to Plan Sponsors. To accomplish retention of these rebate dollars, PBMs disguise rebates as "administrative expenses" or create backdoor arrangements with the "rebate aggregators," to reduce the shared rebate amount with Plan Sponsors.

Plan Sponsors must be cautioned that rebate revenue also drives formulary management. Coupled with the strategy of disguising rebate revenue, PBMs have also generated significant revenue from creating a formulary that substitutes low cost drugs for newer, high cost drugs that pay larger rebates and greater PBM spread pricing but where there is no therapeutic advantage of using brand-name drugs over its generic substitutes.To mitigate such rebate scheme, Plan Sponsors must demand that manufacturer rebates be disclosed and fully distributed back to them.

The reverse auction process does not guarantee cost reduction for Plan Sponsors. Instead, full and complete understanding of the ways in which PBMs secretly generate revenue from Plans, such as spread pricing and rebate schemes, will result in reduction in drug spending. Plan Sponsors should retain counsel that possesses an in-depth knowledge of the PBM industry. ■

About our Plan Sponsor Team

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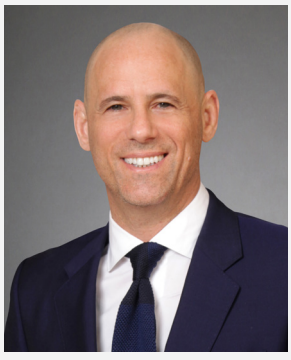
With an in-depth knowledge of PBMs and the Life Sciences space, Frier Levitt provides unique services to Plan Sponsors with the request for proposal process, contract review and negotiation, and audit of PBMs for contract compliance and rebate compliance. Frier Levitt works in Plan Sponsors' best interests, helping to reduce costs and prevent any mistreatment or abusive practices.



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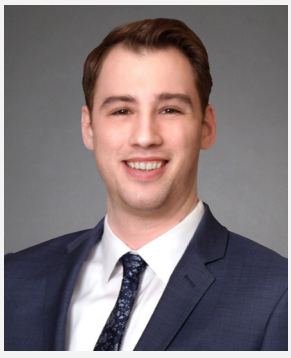

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