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

In this issue:

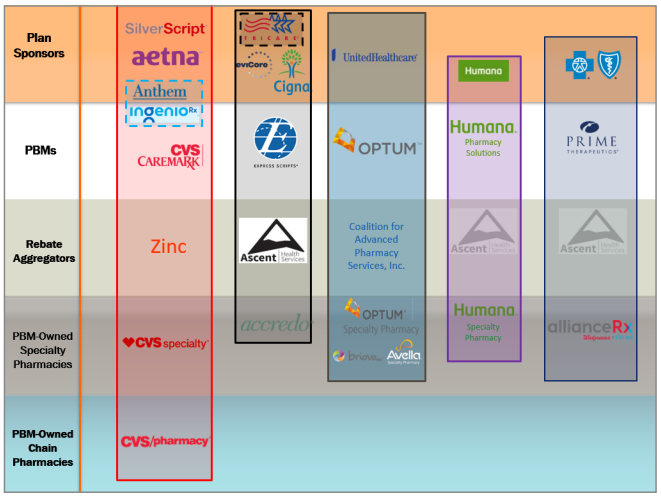
"PBMs are incentivized to select *higher* list price drugs instead of lower list price drugs for their formularies in order to collect a higher rebate…" is one of the Commissioner's important conclusions...

FTC Report on "PBM Rebate Walls" Reveals Impact on Drug Spending, Patient Care and Competition

Authored by Andreas Stargard, Esq., Dae Y. Lee, Pharm.D., Esq., CPBS, Jesse C. Dresser, Esq. and Jonathan E. Levitt, Esq.

This article examines Pharmacy Benefit Manager's ("PBM") "rebate walls" and the impact on the United States drug supply chain.

The Federal Trade Commission head, Commissioner Rohit Chopra, recently issued a report on PBM rebate walls, and this can be seen as a pivotal industry moment. Federal Agencies and Plan Sponsors—the clients of PBMs—are beginning to explore perverse PBM incentives and are waking up to abusive PBM practices. "PBMs are incentivized to select higher list price drugs instead of lower list price drugs for their formularies in order to collect a higher rebate…" is one of the Commissioner's important conclusions. "Because rebating practices from drug companies to PBMs can make it more difficult for new, lower-priced drugs to succeed in the market place, PBMs may actually be causing drug prices to increase, rather than decrease."[1] This so called "Rebate Wall" created by PBMs, among other things, is driving up the drug spending and hindering patients' access to their medications.



Indeed, gross-to-net bubble (i.e., difference in dollars between gross sales of brand name drugs' list prices and their net sales prices after deducting rebates and other discounts) climbed to $175 billion in 2019 and is estimated to exceed $187 billion.[2] The growing trend in the gross-to-net bubble is directly associated with the current structure of the pharmacy industry. More than 77% of prescription claims in the country are processed by the Top 3 PBMs (i.e., CVS Caremark, Express Scripts, and OptumRx). These PBMs have strategically created a complex web of vertically integrated plan sponsors, rebate aggregators, specialty pharmacies, and provider services (pictured above).

The PBM/Insurance Company's vertical integration scenario provides an opportunity and incentivize for PBMs to create rebate arrangements that bring the most financial benefit to themselves, rather than benefiting Plan Sponsors such as private plans and even Medicare and Medicaid Managed Care Organizations ("MCOs"). For example, as we reported here, Broward County (Florida) discovered that OptumRx was not accurately reporting manufacturer drug rebates and, in fact, contracted out its rebate duties to a rebate aggregator (i.e., Coalition for Advanced Pharmacy Services, Inc.), which is a subsidiary of OptumRx's parent company, UnitedHealth Group. The rebate aggregator further sub-contracted with Express Scripts. OptumRx ultimately paid back $833,772 to Broward County, the Plan Sponsor.[3] Also, it is often the case that PBMs exclude prescription claims processed by their own or affiliated pharmacies (e.g., specialty pharmacies and mail-order pharmacies) from rebates. By doing so, rebates that could have been passed onto plan sponsors are staying within PBMs' vertically integrated network.

The "Rebate Wall" also correlates with the sharp increase in patients' out-of-pocket expense, negatively impacting patient care. It was reported that patients' out-of-pocket expense reached $53.7 billion in 2019.[4] High out-of-pocket expenses discourage patients from adhering to their medication regimen. In fact, a study by Kaiser Family Foundation showed that "nearly 1 in 4 Americans who take prescription medications say it is difficult to afford them."[5] Unfortunately, non-adherence leads to unfavorable patient health outcomes and increases healthcare costs.[6] As noted above, PBMs are incentivized to place high-priced medications in the formulary, which in turn, yield higher rebates even if there exist cheaper and therapeutically interchangeable alternatives. For instance, TRICARE's formulary managed by Express Scripts listed Yonsa, a brand-drug used to treat certain cancer, as a preferred-drug and listed a significantly cheaper generic alternative, Zytiga, as a no-preferred, and further required "step-therapy" before allowing patients to try Zytiga.[7]. In the end, Plan Sponsors need to carefully examine the contractual relationship with PBMs and also be aware of both the law and remedies to "check" abusive PBM practices.

Of course, *'Who is on the losing side when PBM companies consolidate into market-dominating giants and then collaborate with drug manufacturers to protect big-pharma profits, to the detriment of lower-cost competitive solutions?'* was not easily answered by the FTC until now, as the agency has historically failed to scrutinize PBM and pharma deals. Yet, a new dawn has come: With the new administration also arrives a novel approach to tackling the immense consolidation that has occurred in the multi-sided PBM marketplace and its interface with the pharma industry. Keep in mind: the underlying principle behind the "PBM concept" was originally meant to serve Plan Sponsors (and ultimately their covered patient lives) by more efficiently managing drug formulary and keeping down the ever-escalating prescription drug costs. In reality, however, the dominant PBMs often coopt big pharma's strategic rebates, designed to make competitive entry more difficult if not impossible for generic alternatives, and reap the resulting benefits for themselves, as opposed to passing them on to their customers, the plan sponsors.

In a refreshing change of tune, in the FTC's report, the federal antitrust watchdog summarizes the dangers as follows: "Rebates can become a 'trap' for payers and providers, causing them to make decisions about coverage and utilization for their beneficiaries due to the financial incentives created by the rebate structure… In this way, some rebates can operate to increase overall drug spending … In addition, rebate walls such as those described above may reduce incentives for biotechnology companies to develop new medicines and/or invest in biosimilars, harming competition and the quality of care available to patients."

Even more promising, Commissioner Chopra issued a separate personal Statement, calling out his agency's prior inaction and the unfettered consolidation and market power of the "three main giants" of the PBM industry. Without hedging his bets, the Commissioner notes that, while PBMs are "supposed to exert their bargaining power on behalf of patients to get better prices on drugs," the industry "suffers from serious conflicts of interest and lack of transparency."

In short, the FTC has finally awakened to the anti-competitive nature of many PBM practices that have plagued the multi-faceted industry for many years. This means that the time to act is now: for plan sponsors, independent pharmacies not affiliated with large PBMs, and competitive drug makers wishing to compete with Big Pharma in these difficult markets. The FTC and (at least some of) its Commissioner have now shown a willingness to listen to antitrust complaints about PBM misbehavior, and their Washington, D.C. office doors are open to all industry players who have valuable information to bring to the enforcers' attention. ■

It is critical for Plan Sponsors to consult with life sciences counsel that demonstrates broad knowledge of PBM contracting before entering into a contract with PBMs. Frier Levitt's Plan Sponsor Practice Group works with Plan Sponsors to ensure they understand the full panoply of their rights under their contracts and applicable law and to ensure that PBMs comply with their contracts and applicable law. If your organization is a Plan Sponsor, ***contact us today****.*

[1] Statement of Commissioner Rohit Chopra Regarding the Commission's Report on Pharmacy Benefit Manager Rebate Walls, available at: https://www.ftc.gov/system/files/documents/public_statements/1590528/statement_of_commissioner_rohit_chopra_regarding_the_commissions_report_on_pharmacy_benefit_manager.pdf

[2] Gross-to-Net Bubble Update: Net Prices Drop (Again) at Six Top Drugmakers, Drug Channels, available at: https://www.drugchannels.net/2021/04/gross-to-net-bubble-update-net-prices.html

[3] Release and Settlement Agreement, available at: https://broward.legistar.com/LegislationDetail.aspx?ID=4082155&GUID=10D06DB1-3526-4885-AFEC-4CFACBD9C7BF&Options=&Search=&FullText=1

[4] Latest CMS Data Reveal the Truth About U.S. Drug Spending, Drug Channels, available at: https://www.drugchannels.net/2021/01/latest-cms-data-reveal-truth-about-us.html

[5] Issue Brief No. 13, Medication Adherence, PAN Foundation, available at: https://www.panfoundation.org/app/uploads/2020/05/Issue-Brief-13_Medication-Adherence.pdf

[6] Id.

[7] COA Letter on Continued Issues Faced by Veterans, Service Members, and Families With TRICARE, Community Oncology Alliance, available at: https://communityoncology.org/coa letter-on-continued-issues-faced-by-veterans/

Growing Number of Actions Taken by Plan Sponsors Against PBMs

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

As we reported here, Plan Sponsors have begun elevating their challenges of Pharmacy Benefit Managers' ("PBMs") and Managed Care Organizations' ("MCOs") conduct, from PBM pricing to auditing and litigating over PBM practices such as "spread pricing". Most recently, a group of Plans initiated a lawsuit against CVS Health Corporation, which owns one of the nation's largest PBMs, Caremark.[1] A similar lawsuit was filed by other Plans against CVS Health in May 2020.[2] These lawsuits reveal a growing willingness of Plan Sponsors to challenge abusive PBM practices and questionable payment arrangements.

In the recent lawsuit, Plans claimed that, among other things, CVS Health overcharged the Plans by intentionally submitting falsely inflated Usual and Customary ("U&C") prices for generic drugs to contracted plans. The Plans argued that CVS Health secretly offered hundreds of generic drugs at low, discounted prices through cash discount programs, but concealed these lower prices to their Plan customers. CVS was supposed to offer its contract Plans the lowest U&C pricing, but allegedly did not. Plans further alleged that Caremark worked with CVS Health to continue the scheme. Plan Sponsors should learn from the practices exposed in these cases and trigger audit provision in their own PBM contracts.

Plans have rights when it comes to pharmacy benefits. Some of these rights include audits and "market check" provisions. PBMs don't make the market check and audit provisions easy to exercise. A Plan Sponsor may be required to obtain PBM approval before using a particular auditor. In more egregious instances, PBMs do not allow the auditor to share any information with the Plan Sponsors. With respect to market provisions, PBMs often include vague contract terms that permit PBMs to reject competitive pricing obtained by Plan Sponsors through the market check process. However, in many instances, Plan Sponsors are able to compile sufficient data points to reveal "overpayments" and/or "lost savings" that were kept by PBMs and their affiliated companies (e.g., Rebate Aggregators, Third Party Administrators, etc.). Plan Sponsors should exercise their contractual and legal rights to audit PBMs and trigger market check provisions, and ultimately pursue legal action against PBMs. ■

Frier Levitt's Plan Sponsor Practice Group provides a panoply of legal services to Plan Sponsors including, without limitation, healthcare policy review and analysis, auditing (and where necessary litigating against) PBMs to verify that Plans have been paid the proper rebates. If your organization is a Plan Sponsor, ***contact us today****.*

[1] CareFirst of Maryland, Inc., et al. v. CVS Health Corporation, et al., Case No. 21-cv-000223, in the United States District Court for the District of Rhode Island.

[2] Blue Cross and Blue Shield of Alabama, et al. v. CVS Health Corporation, et al., Case No. 20-cv-00236, in the United States District Court for the District of Rhode Island.

Smaller "Transparent" PBMs have legal tools to challenge the Mega PBMs in the Request for Proposal Process

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

The United States drug supply chain is dominated by three vertically integrated Pharmacy Benefit Managers ("PBMs") that are owned under the same corporate umbrella as the largest insurance companies, specialty pharmacies and chain pharmacies. In fact, "95% of total U.S. equivalent prescription claims" were processed in 2020 by six PBMs.[1] The Top 3 (CVS Caremark, Express Scripts, Inc., and OptumRx) processed approximately 77% of all claims.[2] Rising drug prices reveal that the primary benefit of this controlled drug environment is enjoyed by the PBMs. The logical result of the vertical integration is that drug pricing is completely opaque and lacks transparency as it relates to PBM "spread pricing", generic drug pricing and whether Plan Sponsors really receive the full benefit of rebates paid by drug manufacturers. "Transparency" is the cure to the problem plaguing our system. Smaller PBMs can effect real change, so long as they understand how to challenge Requests for Proposals ("RFPs").

All Plan Sponsors must understand that major PBMs do not guarantee cost savings. Indeed, several states have commenced legal actions against major PBMs and Plans for overcharging the prescription claims paid by states and taxpayers.

Despite the increasing public outcry and recent legal actions against PBMs, Plan Sponsors (including Self-Funded Employers and Government Agencies) continue to award PBM contracts, through the Request for Proposal ("RFP") process, to a select few PBMs. Plan sponsors should consider "transparent" PBMs who may be able to challenge RFPs that have been awarded to the major PBMs.

Several key factors explain why the major PBMs are able to procure RFP Awards. Plan Sponsors use "brokers" to handle the RFP process. Savvy PBMs provide secretive financial incentives to persuade brokers to recommend the large opaque PBMs. The intelligent use of brokers by large PBMs in the RFP process certainly disadvantages the smaller "transparent" PBMs. But, the smaller PBMs should know that they have tools to level the playing field.

Transparent PBMs must more often challenge RFP Awards through either the administrative process or legal action. For example, with respect to PBM contracts for government-funded plans, the Plan Sponsor is required to comply with certain statutory bidding standards and instruction. "Competitive bidding standards" or "public procurement standards" are derived from statutory law and judge made case law. Where a PBM contract is awarded in violation of these governmental bidding standards, the "losing bidder" may dispute the RFP Award by commencing a dispute in the administrative process in accordance with state statutes and laws. Where the administrative process proves unsuccessful, the losing PBM bidder may file a lawsuit to overturn the RFP Award. Even major PBMs challenge RFP Awards.[3] More specifically, in *Express Scripts Inc. v. Delaware State Employee Benefits Committee*, Express Script alleged that Delaware State Employee Benefits Committee's ("SEBC") RFP Award was contract to RFP and Delaware State procurement law.[4] Smaller PBMs must learn from their much larger competitors in this regard.

All Plan Sponsors must understand that major PBMs do not guarantee cost savings. Indeed, several states have commenced legal actions against major PBMs and Plans for overcharging the prescription claims paid by states and taxpayers.[5] Transparent PBMs should more often challenge RFPs and Plan Sponsors should more carefully consider the RFPs of transparent PBMs. ■

Ensuring a legal RFP process is an important first step toward ensuring transparent contractual arrangements between Plan Sponsors and PBMs. Frier Levitt's Plan Sponsor Practice Group provides a panoply of legal services to Plan Sponsors and transparent PBMs including, without limitation, healthcare policy review and analysis, auditing (and where necessary litigating against) major PBMs to verify that Plans have been paid the proper rebates, and challenging RFP Awards. If your organization is a Plan Sponsor or a Transparent PBM, ***contact us today****.*

[1] The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation, Drug Channels, available at: https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html

[2] Id.

[3] See Express Scripts Inc. v. Delaware State Employee Benefits Committee, Case No. 2021-0434, in the Court of Chancery of the State of Delaware.

[4] Id.

[5] See, e.g., Ohio Department of Medicaid, et al. v. Centene Corp., et al., Case No. 21-cv-01502, in the United States District Court for the Southern District of Ohio.

Cautionary Tale: Plan Sponsors Losing Manufacturer Rebate Dollars to PBMs through Rebate Aggregators

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

As we have reported in prior manufacturer rebate articles[1], Pharmacy Benefit Managers ("PBMs") have created opaque manufacturer rebate arrangements, either directly or through wholly owned subsidiaries. These subsidiaries are "Rebate Aggregators" and they cost Plan Sponsors, beneficiaries, and taxpayers staggering sums of money. Multiple examples of Plan Sponsors being harmed by PBM-owned Rebate Aggregators have been publicly exposed.

In this article, we discuss Lehigh County's audit report that revealed one-sided PBM contract terms that have caused Plans to lose rebate revenue. Plan Sponsors should be aware of rebate arrangements and learn from Lehigh's audit. PBMs generally offer two manufacturer rebate models, which are: (i) a "pass thru" model whereby PBMs ***purport to*** relay 100% of rebates PBMs received, (but in reality, PBM owned Rebate Aggregators retain significant amount of manufacturer rebates); and (ii) a "fixed model" whereby PBMs pay Plans a guaranteed fixed dollar-amount per brand claim regardless of the actual amount of manufacturer rebates PBMs collect. While the fixed rebate model provides minimum rebate guarantees, it may also cap manufacturer rebates that could have significantly lowered a Plan Sponsor's drug spend. Well educated Plan Sponsors can avoid unfair contract terms by active negotiating the rebate provision of the Pharmacy Benefit Management Agreement. Lehigh County's contract was opaque and strongly favorable to the PBM. The Lehigh County's audit report concluded, among other things, that the county could have received in excess of $700,000 in manufacturer rebates during the calendar year ("CY") 2019. The report further notes that if the county had been allowed the option of receiving the higher of actual rebates earned versus a fixed rebate, the total rebate savings for CYs 2017 through 2020 would have been $1.6 million.

Why would the County agree to a fixed rebate arrangement? One likely scenario is that a non-fiduciary benefits broker "facilitated" the PBM—favored terms and conditions. When a broker that is not a "fiduciary" represents a Plan Sponsor in the Request For Proposal ("RFP") process, the resulting contract will likely be advantageous to the PBM. Indeed, the County allowed a broker to select health plans including pharmacy benefits for the County. The County's contract with its plan administrator, Highmark, contained the following unfavorable terms: (i) the contract language prevented disclosure to the County of critical detailed prescription claim data; (ii) the contract terms and conditions were confidential and prevented disclosure of claim data; (iii) any audit (and the actual person performing the audit) was required to be approved by Highmark before the audit was allowed to proceed; and (iv) Highmark refused to disclose contract details such as pricing, claims paid, and other financial details that Highmark entered into with third-parties such as Express Scripts, Inc. In essence, the County was unable to confirm the true amount of manufacturer rebates it should have received through fixed rebate model (regardless of whether the rebates were negotiated and/or administered by Highmark or Express Scripts or Express Scripts' offshore Rebate Aggregator, i.e., Ascent Health Services). Plan Sponsors should avoid the contracting mistakes made by Lehigh County and negotiate contractual terms requiring full PBM transparency. ■

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[1] Frier Levitt Successfully Obtains a $6.25 Million Settlement on Behalf of Its Plan Sponsor Client Against a Pharmacy Benefits Manager, available at: https://www.frierlevitt.com/articles/service/pharmacylaw/recent-successes/frier-levitt-successfully-obtains-a-6-25-million-settlement-on-behalf-of-its-plan-sponsor-client-against-a-pharmacy-benefits-manager/; PLAN SPONSOR UPDATE: Newly Announced Medicare Part D Rebate Rule Is Missing Key Components, available at: https://www.frierlevitt.com/articles/service/pharmacylaw/plan-sponsor-pbm-contract-services/plan-sponsor-update-newly-announced-medicare-part-d-rebate-rule-is-missing-key-components/; Key Items in Pharmacy Benefit Manager Contracts, available at: https://www.frierlevitt.com/articles/service/pharmacylaw/defending-pharmacies-in-pbm-audits/key-items-in-pharmacy-benefit-manager-contracts/; Plan sponsor alert: truths about PBM and manufacturer rebates, available at: https://www.benefitspro.com/2020/05/20/plan-sponsor-alert-truths-about-pbm-and-manufacturer-rebates/; Why Timing Matters When It Comes to PBM Contracting, available at: https://www.managedhealthcareexecutive.com/view/why-timing-matters-when-it-comes-to-pbm-contracting

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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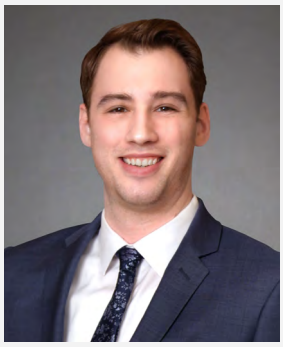

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