

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

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## Jonathan Levitt Invited to Testify Before U.S. Senate Committee on Finance on the Impact of Pharmacy Benefit Managers on Patients and Taxpayers

Frier Levitt has been in the trenches, representing various stakeholders in the drug supply chain, including plan sponsors, pharmacies, dispensing physician practices, hospital and health systems, national provider associations, drug manufacturers, and drug wholesalers for more than two decades, and has been at the forefront of efforts for increased government oversight and scrutiny of PBM conduct.

As a leading voice in the healthcare industry, **Jonathan Levitt** testified to the U.S. Senate Committee on Finance during a hearing on March 30, 2023, titled "Pharmacy Benefit Managers and the Prescription Drug Supply Chain: Impact on Patients and Taxpayers." During his testimony, Jon shared his insights on the role of PBMs in the prescription drug supply chain and their impact on patients and taxpayers. The importance of this hearing for the pharmacy industry cannot be understated.



We invite you to watch the recorded hearing here.

<https://bit.ly/FLPSN1>

Read the press release here. <https://bit.ly/FLPSN2>

Copay maximizers and affiliated PBMs often engage in “double-dipping” by extracting drug rebates in addition to excess discounts through copay assistance programs



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

On January 25, 2023, the Court in *Johnson & Johnson v. SaveOnSP*<sup>[1]</sup> dismissed SaveOnSP's motion to dismiss, allowing Johnson & Johnson's ("JNJ") claims to proceed. JNJ filed a lawsuit against SaveOnSP alleging that JNJ paid \$100M more in copay assistance due to SaveOnSP's misconduct. SaveOnSP filed a motion to dismiss the complaint, but JNJ filed its opposition to the motion. SaveOnSP also met with opposition from Aimed Alliance and Pharmaceutical Research and Manufacturers of America which filed *amicus curiae* in support of JNJ.

The Court's recent order is a significant development, especially as several manufacturers following the JNJ's lawsuit have updated the terms and conditions of their copay assistance programs to restrict (or exclusively carving out) copay maximizer such as SaveOnSP from their programs. JNJ alleges that SaveOnSP inflated patients' copays by reclassifying drugs to avoid copay limits and annual out-of-pocket limits mandated by the US Affordable Care Act ("ACA") to coerce patients into enrolling in the SaveOnSP program and bill the artificially inflated copays to JNJ's copay assistance program. JNJ's complaint also alleges that SaveOnSP worked in partnership with major PBM Express Scripts ("ESI") and ESI's specialty pharmacy Accredo Health Group to operate the program and, in turn, maximize its profits at the expense of both patients and JNJ.

Copay maximizers that operate like SaveOnSP harm patients, providers, manufacturers, and plan sponsors. **Patients** will face higher costs for other healthcare services despite having responsibility for monthly premiums for their health benefits with the expectation that they will be receiving funded coverage for their medications. The dollars extracted by copay maximizers from copay assistance programs will not count towards the patients' deductible or out-of-pocket expenses. **Providers** are harmed because the drugs that are subject to copay maximizer programs are often (if not always) restricted to be filled at PBM-owned pharmacies such as Accredo. **Manufacturers** and the funds they set aside for patient assistance programs are being drained by copay maximizers. More troubling, copay maximizers and affiliated PBMs often engage in “double-dipping” by extracting drug rebates in addition to excess discounts through copay assistance programs. **Plan Sponsors**, including self-funded employers, are also impacted by copay maximizers. The fees imposed by copay maximizers on Plan Sponsors' so-called “savings” (i.e., inflated copays and the amounts extracted by copay maximizers from copay assistance programs) may be higher than the net cost of the drugs.

This lawsuit highlights the ongoing scrutiny of PBMs and their business practices. PBMs are facing increased criticism for their role in rising drug prices and the lack of transparency in their pricing and reimbursement practices. The outcome of this lawsuit will be closely watched by the industry as it could have a significant impact on the pharmacy benefits landscape and how PBMs operate. ■

*Frier Levitt represents manufacturers and plan sponsors with price reporting obligation compliance, including requirements set forth under the Consolidated Appropriations Act, as well as negotiating and drafting rebate agreements with PBMs and evaluating co-pay assistance program requirements and compliance. If you have questions about your organization's reporting obligations or are looking to develop compliant copay assistance programs, contact us to speak with an attorney.*

<sup>11</sup> Johnson & Johnson Health Care Systems, Inc. v. SaveOnSP, LLC., 2:22-cv-02632-JMV-CLW, pending in the United States District Court for the District of New Jersey.

## Pharmaceutical Executive: The Consolidated Appropriations Act and PBM Transparency

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

New federal law introduces significant changes in the design of pharmacy benefit plans with aims to level the playing field between PBMs and their employee healthcare benefit plan clients.

Originally published in [Pharmaceutical Executive](#) on May 12, 2023

Pharmacy Benefit Managers (PBMs) have been extending vertical integration in new and unique ways, leading to significant issues for plan sponsors and plans (referred to as "Plans" collectively). In a new and innovative approach, several large PBMs have created an additional layer between themselves and manufacturers to effectively delegate the collection of manufacturer rebates to "rebate aggregators." Sometimes referred to as rebate GPOs, these mysterious entities include Ascent Health Services, a Switzerland-based GPO that Express Scripts launched in 2019; Zinc, a contracting entity launched by CVS Health in 2020, and Emisar Pharma Services, an Ireland-based entity recently rolled out by OptumRx. Even some of the major PBMs (i.e., the "Big Three" PBMs) sometimes contract with other PBMs' rebate aggregators for the collection of manufacturer rebates as seen in the case of OptumRx contracting with Express Scripts for rebate aggregation for public employee plans. Worse yet, several of these entities have claimed exemption from the federal GPO Safe Harbor, resulting in a lack of transparency, and few limitations of their profitability.

To address these issues and promote fairness, a new federal law has introduced significant changes in the design of pharmacy

benefit plans. It aims to level the playing field between PBMs and their employee healthcare benefit plan clients who have long been taking advantage of Plans through concealed rebate revenue and spread earned by PBMs on inflated drug costs. They impose one-sided contractual provisions on Plans that have opaque terms and conditions. The Consolidated Appropriations Act of 2021 (CAA) marks a major shift in the pharmacy benefits landscape, bringing increased transparency to key aspects of Plan design. The CAA safeguards the rights of Plans and promotes transparency in PBM-Plan agreements.

The CAA amended numerous provisions of the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHA), and the Internal Revenue Code (IRC). Among the most impactful amendments benefiting Plans and Plan Beneficiaries is the increased transparency of prescription drug costs. ERISA was amended to expressly prohibit gag clauses in PBM-Plan contracts. Previously, these gag clauses made it challenging for Plans to access their own benefit data held by PBMs, allowing PBMs to conceal actual reimbursement the PBM paid to pharmacies.

The CAA banished that tool and mandates PBM transparency regarding compensation earned under the PBM-Plan contracts. The amendments expose hidden PBM compensation, and ERISA Plan Sponsors must demand transparency.

Another significant CAA provision regulates PBM compensation under PBM-Plan agreements. ERISA prohibits Plan Fiduciaries from contracting on behalf of the Plan if the arrangement constitutes the furnishing of goods, services, or facilities between the Plan and a “party in interest.” However, ERISA also codifies specific exceptions from the prohibited transactions rule. Plan fiduciaries may contract with PBMs for “services necessary for the establishment or operation of the plan, if no more than reasonable compensation is paid therefor.” It is the responsibility of the Plan Fiduciaries to ensure that PBM contractual arrangements are “reasonable” under ERISA.

The CAA also requires disclosure of compensation that brokers receive. Brokers often receive compensation or incentives from PBMs, and it is not uncommon for brokers to get paid more as the Plan Sponsor’s total drug spend increases. PBMs often pay brokers “per member per month” fees and other consulting fees that prevent

brokers from acting on the Plan Sponsor’s best interest. Brokers earn revenues in several different ways, not just through direct fees paid by the Plan Sponsor. Overrides, commissions, bonuses, fees from Third Party Administrators (TPAs), fees paid by PBMs, prescription fill fees, shared savings from plan providers, etc. are all different ways brokers are likely compensated secretly by PBMs. These revenues are typically not disclosed to the Plan Sponsor, which is a conflict of interest that should be avoided.

To fully leverage the benefits provided in ERISA, Plans must demand full descriptions of direct and indirect compensation, as well as the sources of compensation, that the PBM, affiliate, and/or subcontractor will receive related to performing under the contract. Indirect compensation refers to fees that are received from a third party, such as commissions, but not directly from the Plan sponsor or service provider. It is important for Plan Sponsors and Fiduciaries to understand the nature and amount of indirect fees associated with their prescription drug benefits plans, and to ensure that they are reasonable. This will allow Plans to safeguard their rights and promote transparency in PBM-Plan agreements, providing increased transparency on key aspects of Plan design. ■

## Did the Inflation Reduction Act Spare PBMs?

The Inflation Reduction Act of 2022 (the “Act”), signed into law on August 16, 2022, contains several provisions aimed at reigning in prescription drug costs for Medicare beneficiaries. From a high level, these provisions include the imposition of an inflationary rebate on certain drugs under Medicare Part B and D, Medicare Part D redesign intended to close the oft-criticized coverage gap (also called the “donut hole”), temporary Medicare Part B payments for certain biosimilar products, a cap on cost-sharing for covered insulin products, and the elimination of cost-sharing obligations for certain vaccines administered under Part D.

*Authored by Jesse C. Dresser, Esq., Dae Y. Lee, Pharm.D., Esq., CPBS and Matthew A. Benzoni, Esq.*

Perhaps the most consequential change—one that represents a seismic shift in a policy that has spanned decades—is the Act’s authorization of the Secretary of Health & Human Services (“HHS”) to negotiate certain “high spend” drugs, administered under Part B and D, directly with manufacturers and on behalf of the government. As a consequence, the Act presents implications for the pharmaceutical sector that are undoubtedly significant.

Yet, while the Inflation Reduction Act seeks to reset the course of prescription drug pricing in the United States, to what extent does it address the role of Pharmacy Benefit Managers (“PBMs”)—organizations that many consider a primary driver of these run-away costs? Unfortunately for patients who rely on affordable

medicines to stay alive and healthy, the answer is “very little.” In fact, Congress refers to PBMs only twice in the Act.

The omission of any PBM regulation from the Act is significant when considering some of the more egregious tactics put into practice by the PBMs. Spread pricing, for example, occurs when PBMs charge plan sponsors a higher price for a patient’s medication than they pay the dispensing pharmacy, and keep the difference, known as the “spread,” for themselves. It is one of the many schemes employed by PBMs leading to unnecessary financial strain for payers and patients. Another example involves rebate aggregators that are wholly owned by PBMs. Unbeknownst to plan sponsors,

## Did the Inflation Reduction Act Spare PBMs?...continued

PBMs delegate the rebate aggregation function to their rebate aggregators, and therefore do not pass on the rebates that are due and owed to plan sponsors.

This article will explore the potential impact of the Act on these questionable PBM practices should any exist, as well as the economic implications for prescription drug pricing in light of the Act's shortcomings.

### Price Negotiation for High-Spend Single-Source Medicare Drugs

Among the Act's key provisions is the authorization of HHS to negotiate Maximum Fair Price ("MFP") for certain high-spend single-source Medicare Parts B and D drugs and biologics.<sup>[1]</sup> A qualified single source drug is one that was approved at least seven years prior to selection and for which it is not the reference listed drug for a generic approved via Abbreviated New Drug Application. Though negotiated prices will not apply until 2026, initial negotiations begin in 2023 when the Secretary publishes a list of selected drugs.<sup>[2]</sup> Importantly, during the negotiations, the Secretary must consider a number of statutorily prescribed factors including, but not limited to, research and development costs of the manufacturer for the drug, current unit costs of production and distribution of the drug, and market data for the drug in the United States.

Without specific reference, the Act ostensibly removes PBMs from their role in negotiating eligible drugs under Medicare. While reducing the PBMs' role in the drug channel is a step forward, the prohibition is limited in that PBMs still hold substantial leverage over drug prices, and drug price negotiations, outside of Medicare. It simply will not change what PBMs are permitted to do in other markets where they dictate which drugs make it onto their formularies or engage in other tactics (such as step therapy) to favor drugs that are financially beneficial to them.

At the core of the high drug pricing are manufacturer rebates; a lucrative tool used by PBMs to provide manufacturers with a favorable position on their formularies even over lower cost, but equally effective, generic drugs. Over time, manufacturers have had to increase list prices of prescription drugs to sustain ever-increasing rebate dollars. Drugs with low competition, however, present a low rebate opportunity for PBMs. Under the Act, drugs eligible for negotiation inherently face low competition. Therefore, it follows that even pre-IRA, currently eligible drugs would have presented low rebate opportunities for PBMs to exploit.

One on hand, due to the low rebate potential for negotiation-eligible drugs, PBMs will have little incentive to make up lost Medicare revenue in other markets. On the other, the Act does very little to remedy abusive rebate practices that have become endemic to prescription drug pricing under any other circumstances.

On November 30, 2020, the Office of Inspector General ("OIG") promulgated a final rule to revise the Federal Anti-Kickback Statute's discount safe harbor. More specifically, the final rule modified the existing discount safe harbor by exempting "fixed fees that manufacturers pay to PBMs for services rendered to the manufacturers that meet specified criteria."<sup>[3]</sup> In other words, the final rule would have ended safe harbor protections from AKS liability for rebates negotiated between drug manufacturers and PBMs or plan sponsors in Medicare Part D. The IRA will delay implementation of the final rule until 2032.<sup>[4]</sup>

Though rebate schemes are a core issue at the heart of questionable PBM practices, replacing drug rebates with fixed service fees under the safe harbor does not fix the systematic issues in the Medicare Part D space. Frier Levitt has written extensively on the shortcomings of this final rule, concluding that HHS has failed to demand complete transparency from PBMs in terms of their rebate aggregation. It is often the case that plan sponsors are not aware of PBMs' wholly owned rebate aggregators. Instead, PBMs use their rebate aggregators to keep the rebates that should've been relayed to plan sponsors. This lack of transparency is problematic because safe harbor protection is offered only for service fees related to pharmacy benefit management services provided by the PBMs to Part D plan sponsors.

Thus, the IRA's moratorium on implementation of the final rule is commendable if only for the fact that, from its inception, would have failed to reign in abusive PBM practices, particularly those effecting Part D sponsors.

### Conclusion

In passing the Inflation Reduction Act, Congress set in motion its electoral mandate to reign in the cost of prescription drugs and healthcare generally. With the IRA, however, comes added complexity and certain shortcomings. More specifically, it fails to effectively reign in questionable PBM practices particularly those relating to spread pricing and rebate programs. Notwithstanding, compliantly navigating the IRA in its current form, particularly with respect to its pricing provisions, is going to be of critical importance in the new year. Though negotiated prices will not apply until 2026, initial negotiations begin in 2023 upon the Secretary's publication of selected drugs. ■

<sup>[1]</sup> H.R. 5376, 107th Cong. § 11301, codified at 42 U.S. Code § 1320f.

<sup>[2]</sup> Id.

<sup>[3]</sup> 85 Fed. Reg. 76,666, 76,667 (Nov. 30, 2022).

<sup>[4]</sup> H.R. 5376, 107th Cong. § 11301.

*Frier Levitt's Life Sciences Group offers a range of legal services including healthcare policy review and analysis, representation of plan sponsor clients in legislative matters, and auditing of PBMs to ensure that plans have received the correct rebates. In addition, Frier Levitt counsels drug manufacturers seeking to implement drug pricing programs compliant with federal law, including the computation and negotiation of negotiate Maximum Fair Price (MFP) under the IRA. For more information or questions about our legal services for plan sponsors and manufacturers, contact us.*

# CAA Alters Landscape for Self-Funded Plans and Creates Opportunities

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



A new federal law has brought significant change in the design of pharmacy benefit plans, leveling the playing field between pharmacy benefit managers (“PBMs”) and their employee healthcare benefit plan (“Plan”) clients. For far too long, PBMs have taken advantage of Plans by concealing rebate revenue and spread earned by PBMs on inflated drug costs. They impose one-sided contractual provisions on Plans that have opaque terms and conditions. Fortunately, the Consolidated Appropriations Act of 2021 (the “CAA”) introduces a major shift in the pharmacy benefits landscape, providing increased transparency on key aspects of Plan design. The Consolidated Appropriations Act of 2021 (“CAA”) not only safeguards Plans’ rights and also promotes transparency in PBM-Plan agreements.

The CAA amended numerous provisions of the Employee Retirement Income Security Act of 1974 (“ERISA”), the Public Health Service Act (“PHA”), and the Internal Revenue Code (“IRC”). Perhaps the most impactful amendment benefiting Plans and Plan Beneficiaries is the increased transparency of prescription drug costs. ERISA was amended to expressly prohibit “gag clauses” in PBM-Plan contracts. A “gag clause” is a PBM tool making it difficult for Plans to access their own benefit data in the possession of PBMs. Gag clauses allowed PBMs to conceal actual reimbursement the PBM paid to pharmacies. The CAA banished that tool. The single most impactful amendment requires PBMs to be transparent as to compensation earned under the PBM-Plan contracts. The CAA amendments expose hidden PBM compensation, and ERISA Plan Sponsors must demand transparency.

## PBM-Plan Agreements Under ERISA: Reasonable PBM Compensation is Now the Law

Perhaps the most impactful CAA provision regulates PBM compensation under PBM-Plan agreements. ERISA prohibits Plan Fiduciaries from contracting on behalf of the Plan if the arrangement constitutes the furnishing of goods, services, or facilities between the Plan and a “party in interest.”<sup>[1]</sup> “Party in interest” is defined to include any person or corporation “providing services to such plan.”<sup>[2]</sup> Thus, these provisions would prevent a Plan Fiduciary from contracting for PBM services on behalf of the Plan. However, ERISA also codifies specific exceptions from the prohibited transactions rule. Specifically, Plan Fiduciaries may contract with PBMs for “services necessary for the establishment or operation of the plan, **if no more than reasonable compensation is paid therefor.**”<sup>[3]</sup> Accordingly, it is the responsibility of the

Plan Fiduciaries to ensure that PBM contractual arrangements are “reasonable” under ERISA; which begs the question—what makes a PBM-Plan arrangement reasonable?

Critically, ERISA now expands on the reasonableness requirement, and codifies certain requirements that must exist for a PBM-Plan arrangement to be considered reasonable. For example, a PBM-Plan contract cannot be considered reasonable unless the PBM discloses, in writing, the following:

Gag clauses allowed PBMs to conceal actual reimbursement the PBM paid to pharmacies.

- A description of services to be provided to the Plan pursuant to the contract;
- A statement that the PBM, an affiliate, or a subcontractor will provide, or reasonable expects to provide, services pursuant to the contract or arrangement directly to the Plan **as a fiduciary**;
- A description of **all direct compensation, either in aggregate or by service, that the PBM, an affiliate, or subcontractor expects to receive in connection with the services provided**;
- A **description of all indirect compensation** that the PBM, an affiliate, or a subcontractor reasonably expects to receive in connection with the services described, including a description of the arrangement between the payer and the PBM, affiliate, or subcontractor, as applicable, pursuant to which indirect compensation is paid;

One common tactic deployed by PBMs that can now be uncovered and prevented is spread pricing. Spread pricing occurs when a PBM reimburses a dispensing pharmacy at a price lower than the price paid by the Plan to the PBM for the same claim.

- **A description of any compensation that will be paid among the PBM, an affiliate, or a subcontractor in connection with the services** if compensation is set on a transaction basis (such as commissions, finder fees, or other similar incentive compensation based on business placed or retained), including identification of the services for which such compensation will be paid and identification of the payers and recipients of such compensation (including the status of the payer and recipient as an affiliate or subcontractor); and
- A description of any compensation that the PBM, an affiliate, or a subcontractor expects to receive in connection with termination of the contract or arrangement, and how any prepaid amounts will be calculated and refunded upon such termination.<sup>[4]</sup>

In addition, ERISA requires PBMs to furnish, upon written request from the Plan, to furnish any other information related to compensation received by the PBM in connection with the contract that is required for the Plan to comply with its reporting requirements under the CAA.<sup>[5]</sup>

### Opportunities for Plans

The importance of the requirements outlined above cannot be overstated, as they provide Plans with tools and the power to gain greater insight into PBM business operations. In turn, these requirements allow Plans to negotiate transparent PBM contracts. To capitalize on the advantages contained in ERISA, Plans must demand full descriptions of direct and indirect compensation, as well as the sources of compensation, that the PBM, affiliate, and/or subcontractor will receive related to performing under the contract. Indirect compensation refers to fees that are received

from a third party, such as commissions, but not directly from the plan sponsor or service provider. It is important for plan sponsors and fiduciaries to understand the nature and amount of indirect fees associated with their prescription drug benefits plans, and to ensure that they are reasonable and properly disclosed. Only by utilizing these rights can Plans ensure they are receiving all financial savings to which they are rightfully entitled.

One common tactic deployed by PBMs that can now be uncovered and prevented is spread pricing. Spread pricing occurs when a PBM reimburses a dispensing pharmacy at a price lower than the price paid by the Plan to the PBM for the same claim. For instance, a pharmacy dispenses a prescription to a Plan beneficiary and receives \$10 in reimbursement from the PBM for dispensing the drug. In turn, the PBM charges the Plan \$15 for the same prescription claim and retains the \$5 difference (i.e., the spread) as profit. Spread pricing costs Plans potentially millions of dollars in excess drug spend. For example, Centene Corporation (“Centene”) and its subsidiary companies which included PBMs and Managed Care Organizations, engaged in multiple tactics, including spread pricing in their contracts with state Medicaid programs. Centene not only settled with several Medicaid agencies but also reserved over \$1 billion for future settlements.

Another source of compensation PBMs keep hidden from Plans involves manufacturer rebates. Major PBMs own rebate aggregators including Ascent Health Services (owned by Cigna/Express Scripts), Emisar (UnitedHealth/Optum), and Zinc Health Services (CVS Health/Caremark). PBMs often include terms in their agreements with Plans that mislead Plans into believing they are receiving 100% of rebates. However, PBMs fail to disclose their use of subcontracted or affiliated rebate aggregators, and the portion of rebates retained by these rebate aggregators. In turn, PBMs deceive Plans into believing they are receiving 100% of rebates when, in reality, significant portions of rebates are retained by the PBM’s rebate aggregators. To make matters worse, these rebate aggregators are often owned by or affiliated with PBMs, leading to additional PBM hidden revenues. Importantly, thanks to the mandatory disclosures under ERISA, Plans have insight into PBM/rebate aggregator relationships and, potentially, an opportunity to discover any rebate dollars being wrongfully retained by rebate aggregators and/or PBMs. ■

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*Frier Levitt's Plan Sponsor Practice Group provides a host of legal services for health plans and plan sponsors, including reviewing and analyzing PBM contracts, negotiating and drafting PBM contracts, auditing (and where necessary, litigating against) PBMs to verify that they are abiding by the terms set forth in the PBM contracts, and demanding access to Plan data to uncover any hidden cash flows retained by PBMs. If your organization is a plan sponsor, contact us to learn more about your contractual rights and obligations.*

# CAA Alters Landscape for Self-Funded Plans and Creates Potential Pitfalls

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



The Consolidated Appropriations Act of 2021 (the “CAA”) levels the playing field between pharmacy benefit managers (“PBMs”) and their employee healthcare benefit plan clients (“Plans”) by creating new transparency and compensation requirements for PBMs. The CAA established new opportunities for Plans by providing resources to uncover hidden PBM cash flow. Alongside the new tools at Plans’ disposal, the CAA has also created additional responsibilities to which Plans and their fiduciaries must adhere. Failure to comply with these new obligations exposes both the Plan and its fiduciaries to potential liability.

## Reporting Obligations

Under the CAA, Plans must submit considerable amounts of data to the United States Department of Treasury, Department of Labor, and Department of Health and Human Services (collectively, the “Departments”) on an annual basis. Reports must be submitted by June 1 of the year immediately following the “reference year,” meaning data reports for the year 2022 are due June 1, 2023. While the onus is on Plans to submit the annual reports, Plans often do not have access to the data they are required to report—particularly the data on prescription drug spend and rebates. As such, the CAA allows Plan service providers and vendors, such as third-party administrators (“TPAs”) and PBMs, to submit the required data on their behalf. In fact, the Departments expect PBMs and TPAs to be the entities predominantly submitting the required reports. However, it is ultimately the Plan that remains liable for ensuring the data is reported and reported accurately.

Consequently, Plans should have already confirmed with their PBMs and TPAs that reports for reference years 2020 and 2021 were properly submitted by the extended deadline of January 31, 2023. Moving forward, Plans need to negotiate terms into their agreements with PBMs or other vendors obligating these service providers to submit the annual reports in a timely and accurate manner. Failure to take these proactive measures only exposes

the Plan to sanctions, as PBMs and TPAs are not subject to any liability for reporting errors under the CAA.

## Fiduciary Duties and Auditing

Amongst the sweeping changes introduced through the CAA, the most impactful are the disclosure and reasonable compensation requirements discussed in our recent article, “CAA Alters Landscape for Self-Funded Plans and Creates Opportunities”. These requirements obligate service providers like PBMs to disclose all sources of direct and indirect compensation they or any of their affiliates or subcontractors will receive in connection with providing services to the Plan. Further, the CAA prevents Plan fiduciaries from entering into agreements with service providers unless the service provider’s compensation is reasonable. While the mandatory disclosures of compensation required under the Employee Retirement Income Security Act of 1974 (“ERISA”) provide a valuable tool to Plans, Plan fiduciaries cannot simply rely on these disclosures to ensure their arrangements with PBMs are reasonable and compliant with ERISA as amended by the CAA. Rather, Plan fiduciaries must routinely monitor PBMs to ensure they only receive compensation as disclosed—a task that can only be completed through regular PBM audits.

In fact, a failure to routinely audit PBMs to confirm the reasonableness of PBM arrangements may expose Plan fiduciaries to potential liability for breaches of fiduciary duties. Under ERISA, Plan fiduciaries are obligated to discharge their duties solely in the interest of Plan participants and for the exclusive purpose of defraying reasonable expenses of administering the Plan. [1] As such, Plan fiduciaries are obligated to regularly monitor service providers like PBMs to confirm the expenses connected to the PBMs’ services are reasonable. Plan fiduciaries which

Plan fiduciaries must routinely monitor PBMs to ensure they only receive compensation as disclosed

fail to uncover egregious PBM practices like spread pricing and rebate manipulation can potentially be held liable for breaches of co-fiduciary duties. Indeed, ERISA creates liability for a Plan fiduciary that fails to comply with their own fiduciary obligation (e.g., monitoring/auditing service providers like PBMs) and, as a result, enables another fiduciary to commit a breach.[2] Therefore, since ERISA now requires PBMs to expressly state they are providing services to the Plan as a fiduciary, if a Plan fiduciary's failure to effectively audit a PBM enables the PBM to retain hidden cash flows at the expense of the Plan, the Plan fiduciary could potentially be held liable for breach of co-fiduciary duties. Consequently, while the mandatory disclosures under ERISA are a great starting point

for Plan fiduciaries, Plan fiduciaries must nonetheless audit PBMs regularly to ensure the Plan is receiving the benefit of its bargain. ■

*Frier Levitt's Plan Sponsor Practice Group has a proven track record of obtaining favorable results for health plans and plan sponsors in various areas, including review and analysis of PBM contracts, negotiation and drafting of PBM contracts, auditing (and where necessary, litigation against) PBMs to verify that they are abiding by the terms set forth in the PBM contracts, and demanding access to Plan data to uncover hidden cash flows retained by PBMs. If you are a health plan or plan sponsor organization, contact us to learn more about your contractual rights and obligations under the CAA.*

## FTC Expands PBM Investigation to PBM-Owned Rebate Aggregators/GPOs

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

In a significant development that could impact the future of prescription drug costs, the U.S. Federal Trade Commission ("FTC") announced an expansion of its investigation into the country's leading Pharmacy Benefit Managers ("PBMs").

The investigation now includes two group purchasing organizations, (GPOs) commonly known as Rebate Aggregators. This move comes almost a year after the FTC commenced a 6(b) study and sent binding information demands to CVS Caremark, Express Scripts, Inc., Humana, Inc., MedImpact HealthCare Systems, Inc., OptumRx, Inc., and Prime Therapeutics, LLC. On May 17th, the FTC issued

additional compulsory orders to Zinc Health Service, LLC ("Zinc") and Ascent Health Services, LLC ("Ascent") as part of its probe into how PBMs affect pricing of prescription drugs. This expansion signals the FTC's determination to thoroughly investigate the role of PBMs and Rebate Aggregators in the drug supply chain.

In recent years, all 50 states have enacted legislation aimed at regulating PBMs and their practices.

Ascent and Zinc, the two Rebate Aggregators under investigation, are wholly owned by Cigna/Express Scripts and CVS Health/Caremark.

UnitedHealth/OptumRx also owns rebate aggregators, Coalition for Advanced Pharmacy Services, LLC and Emisar Pharm Services, LLC. It is worth noting that Ascent is based out of Switzerland and Emisar is based out of Ireland.

**Rebate Aggregators and their Role:** Rebate Aggregators negotiate rebates with drug manufacturers on behalf of PBMs or plan sponsors and hold the contracts governing these rebates. Rebates are supposed to be passed through to the plan sponsors, but instead contribute to fueling PBM profits. Rebate aggregators demand money (rebates) from drug manufacturers in exchange for the PBM's promise to place the manufacturer's product on the PBM's drug formulary. Rebates are supposed to be used to reduce the expense of prescription drugs for PBM clients (i.e., plan sponsors) and patients. However, Rebate Aggregators retain unknown portions of rebates as profits. Patients and plan sponsors pay the price.



**FTC Investigation Focus:** The FTC's initial investigation, launched in June 2022, aimed to unravel the facts behind the PBMs' role in setting sky-high prescription drug prices. The secrecy behind rebates is mainly because of the vertical integration of PBMs, the country's largest health insurance companies, Rebate Aggregators, and wholly-owned mail order and specialty pharmacies. The FTC's investigation focuses on fees that PBMs charge, efforts to steer patients toward PBM-owned pharmacies, abusive pharmacy audit practices, pharmacy reimbursement methods, and negotiations of rebates and fees with drug manufacturers that skew formulary incentives and prescription drug costs for health plan payors and patients.

**Impact of Including Rebate Aggregators:** The inclusion of Rebate Aggregators in the investigation is expected to provide the FTC with greater insight into manufacturer rebate arrangements and their impact on plan formulary design and drug costs. Specifically, because manufacturers often pay the highest rebates for their most expensive products, PBMs are incentivized to include high-cost products on their formulary. Consequently, health plans and patients are burdened with higher prices, even when lower cost generic equivalents are available. The FTC's investigation was launched in part due to patient and physician complaints that PBMs routinely interfere with patient care by imposing insurance approval requirements (e.g., prior authorizations) before a patient proceeds with specific medications and treatments.



The FTC's initial investigation, launched in June 2022, aimed to unravel the facts behind the PBMs' role in setting sky-high prescription drug prices.

**Legislative Reform and Federal Commitment:** The FTC's examination of PBMs and Rebate Aggregators comes amid significant legislative reform throughout the country aimed at addressing abusive PBM conduct. Indeed, in recent years, all 50 states have enacted legislation aimed at regulating PBMs and their practices. Likewise, there is significant momentum at the federal level, as Congress actively attempts to pass reformative legislative. Frier Levitt co-founding partner, Jonathan Levitt, Esq., recently testified before a United States Senate Finance Committee where he discussed the consequences of PBM and Rebate Aggregator tactics like rebate manipulation and the impact on patients, health plans, and taxpayers.

The combination of Congressional motivation to pass impactful legislation and intensified executive enforcement efforts by the FTC illustrate the federal government's commitment to take meaningful steps toward reforming the pharmacy benefits industry.

**Ensuring Proper Utilization of Rebates:** Given the expanded investigation by the FTC and increased scrutiny from the legislators against PBMs, drug manufacturers and plan sponsors are advised to carefully review their agreements with PBMs to ensure that rebates are effectively utilized to reduce the drug spend and patients' out-of-pocket costs. As we discussed here, plan sponsors have a duty to monitor their PBMs' performance and ensure that fees paid to the PBM are reasonable. ■

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*Frier Levitt is at the forefront of federal and state efforts to combat PBM abuses. Our experienced attorneys collaborate with legislators at state and federal levels to shape legislation aimed at addressing PBM abuse for various industry stakeholders. Frier Levitt's Plan Sponsor Practice Group has a proven track record of obtaining favorable results for health plans and plan sponsors in various areas, including, but not limited to, analyzing PBM contracts and initiating actions against PBMs to access Plan data to ensure PBM compliance or recover savings wrongfully withheld by the PBM. Contact us to learn more.*

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

# Navigating New Laws: Employers' Crucial Choice "To Sue or Not to Sue" Brokers, Third Party Administrators, and PBMs

Shakespeare's Hamlet uttered "to be or not to be, that is the question". Well, large employer groups face a new question, "to sue or not to sue". Perhaps a little dramatic, but in the rapidly evolving landscape of healthcare and drug supply chain, employers are confronted with the difficult choice of taking no action and facing their employees' "slings and arrows", or taking legal action under the Consolidated Appropriations Act ("CAA"). This article explores the choices.

Massive changes in the law are impacting stakeholders in the healthcare and drug supply chain. Change is good for some, bad for others. This diverse group of stakeholders includes drug manufacturers, medical providers, pharmacies, insurance companies, brokers, Pharmacy Benefit Managers ("PBMs"), large employers ("plan sponsors") and their employees. Among these stakeholders, plan sponsors are stepping up to safeguard their rights and the results could be a "win" for employers and their employees. Plan sponsors are taking decisive action to protect their rights and fulfill their duties to employees. A significant surge of lawsuits against brokers/third party administrators (collectively, "Consultants"), insurance companies and PBMs signals a growing momentum to hold insurers accountable for mismanagement of medical and drug spending. Additionally, plan sponsors are exploring undisclosed broker fees through litigation and arbitration.

Recently, Kraft Heinz Co.'s ("Kraft") employee benefit plan filed a lawsuit against Aetna Life Insurance Co. ("Aetna") in Texas federal court. Kraft alleges that Aetna mismanaged Kraft's health and dental plans by pocketing undisclosed fees and wrongfully approving millions of dollars in claims. Kraft further alleges that Aetna violated Employee Retirement Income Security Act of 1974 ("ERISA") by improperly leveraging its role as Kraft's third-party administrator to generate \$1.3 billion in excess profits. Kraft sued after it asked for its employees' claims data and Aetna allegedly provided incomplete data and edited bills from a specific time frame.

The CAA provides employers access to data previously beyond their grasp. Employers are becoming more aware of fees charged and claims paid, leading to increased scrutiny and legal action. *Kraft v. Aetna* is just one of many lawsuits expected to be filed by employers and plan sponsors against Consultants, PBMs, and insurers.

Many employers are taking a stand against the Consultants and plan administrators, demanding transparency and accountability in the management of their health plans. As legal action unfolds, it remains to be seen how these cases will shape the landscape of employer-sponsored health plans. To protect their fiduciary duties and the best interests of their employees, employers must ensure they have access to claims data and review their agreements with the Consultants, plan administrators and PBMs.

Employers that do not actively seek out and analyze this data, may be sued by employees, accusing them of breaching their fiduciary duty. In the same vein, inactive employers will be vulnerable to employee lawsuits based on a "breach of fiduciary duty" claim.

Employers are becoming more aware of fees charged and claims paid, leading to increased scrutiny and legal action.

Employers seeking to avoid claims can effectively close the door for employee litigation. Taking "no action" has consequences. This emerging litigation trend includes employees pursuing litigation against employers. We have seen a wave of law firms actively seeking employee/plaintiffs against their employers regarding health plans.

Whether the new laws are "a sword or a shield" will depend on the employer action. ■

*Frier Levitt has extensive experience representing plans and plan sponsors in negotiations, audits, litigation and arbitration with PBMs. Our firm has observed the unethical practices of PBMs and the negative impact they have on healthcare and life sciences industry stakeholders, including plan sponsors. If you are a plan sponsor facing PBM contract issues or experiencing other issues with a PBM, contact Frier Levitt to speak with an experienced member of our team. We can provide comprehensive support and legal guidance tailored to your specific needs.*

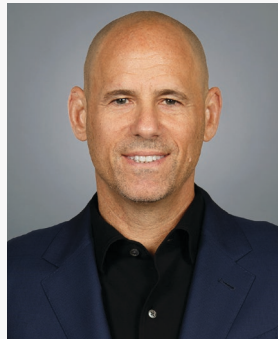
## About Frier Levitt

Frier Levitt is a premier boutique law firm with offices in New York and New Jersey. Firm attorneys are leaders in the industry and provide an array of services to healthcare and life sciences clients nationally. Frier Levitt serves the provider community, wholesalers, manufacturers and plan sponsors, large physician group practices, hospitals, hospital medical staffs, ambulatory surgery centers, and laboratory companies.

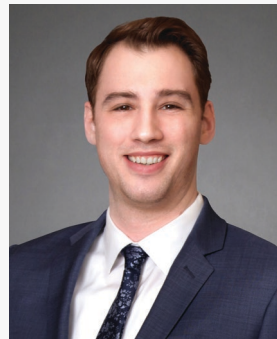
Frier Levitt's Plan Sponsor Practice Group provides a host of legal services to plan sponsors including reviewing and analyzing PBM contracts, negotiating and drafting PBM contracts, and auditing (and where necessary, litigating against) PBMs to verify that PBMs are abiding by the terms in the PBM contracts.

## Our Plan Sponsor Team Leaders

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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