November 30, 2017

Please accept the following submission on behalf of the National Community Pharmacists Association (NCPA) in response to the call for public comment following the Federal Trade Commission public workshop entitled *Understanding Competition in Prescription Drug markets: Entry and Supply Chain Dynamics* held on November 8, 2017.

NCPA would like to focus the content of this submission on the role that intermediary pharmacy benefit managers (PBMs) play in the drug supply chain and their influence on drug pricing and consumer access to medications. In addition, our comments will also highlight the overall lack of transparency that currently exists with respect to many PBM business practices and revenue streams. Finally, NCPA would like to offer some potential policy recommendations that could bring increased transparency to the PBM marketplace and empower PBM consumers or customers to make more informed financial decisions to the benefit of their covered beneficiaries.

BROAD BASED CONCERN REGARDING DRUG PRICING

Currently there is broad based national concern over drug pricing voiced by consumers and policymakers alike. There are an increasing number of high deductible health plans, and many of these plans require that the insured pay a "coinsurance" amount—which means that they must pay a percentage of the cost of the drug. Combine this dynamic with the high sticker price of many new, specialty drugs and you have many patients and consumers that are being held responsible for extremely large prescription costs. Consumers are now motivated to try to determine the reason for these high costs which has compelled many policymakers to cast new light on the drug supply chain as a whole—not simply drug manufacturers—but also on PBMs.

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PBMs INFLUENCE FORMULARY AND PLAN BENEFIT DESIGN WITHOUT A CORRESPONDING FIDUCIARY DUTY

PBMs have a unique vantage point in the middle of the supply chain to have access to critical claims and financial data by virtue of their contracts with manufacturers and pharmacies and also due to their multitude of revenue streams. PBMs negotiate rebates with pharmaceutical manufacturers. These rebate negotiations also determine which drugs are included on PBM formularies and ultimately what drugs patients will have access to and at what cost. PBMs also contract with employers to manage their prescription drug benefit and in doing so, heavily influence prescription drug benefit designs. PBMs typically enter into contracts in which they will assume no fiduciary duty to employers or plan sponsors, which means that the PBM has no affirmative duty to disclose the fact that certain plan benefit designs may financially enrich the PBM or the fact that the PBM may be profiting from the sale of claims data derived from that plan sponsor. Ultimately, without any fiduciary obligation, there is no transparency or accountability for PBM conduct.

CRITICAL NATURE OF DEFINITIONS IN PBM CONTRACTS ("brand," "generic," "specialty," rebate,")

Typically, PBMs will claim that employers are "sophisticated purchasers" and that PBMs simply implement what the employer or plan sponsor requests. In reality, because of the fact that the drug supply chain and drug pricing is so complicated, employers hire PBMs precisely because they need help navigating this territory and rely heavily on them for help with plan benefit design. Despite this reliance on the PBM, employers frequently express frustration with the complexity and lack of transparency of their contracts. The language of these contracts and definitions utilized are of paramount importance and can have profound downstream effects on both patients and pharmacies.

For example, some key definitions in these contracts are those for "brand drug," "generic drug," or "drug classification" (how parties agree whether or not to classify a drug as a brand or a generic) and "specialty drug." When there are no definitions for these terms, the PBM is free to interpret these any way they wish. Also, many times even if they are defined—they are drafted in such a way that enables the PBM to classify many drugs as either a brand or a generic. Many definitions of "generic drug" simply state that it is any drug for which there are a "sufficient number of suppliers" and the PBM is the ultimate arbiter of exactly what "sufficient" means. In addition, under many definitions of "brand drug," single source generics are considered brands. Also, many PBMs classify drugs differently over the life of the contract itself because most contracts are silent as to whether drug classifications must be consistent throughout the contract. A PBM may wish to "increase" its generic substitution rate and then recharacterize drugs they initially invoiced as "brands" as "generics." Alternately, if a contract calls for a PBM to pay a specified rebate "per brand drug claim," it can reclassify drugs that were invoiced as brands as generics for the purpose of calculating rebates.

Another critical definition in PBM contracting is that of "specialty drug." There is currently no standardized definition of specialty drug and many PBMs attach specialty drug lists to contracts with PBM clients that are subject to change at the sole discretion of the PBM. The inclusion or exclusion of certain drugs from these lists—directly impacts the availability of these drugs to patients—and are directly tied to the fact that many PBMs own their own mail order specialty pharmacies. The classification of a certain product as "specialty" also has important price and cost sharing implications for patients as well. Many drugs that are deemed specialty drugs are high dollar medications and PBMs have significant motivation to funnel these prescriptions to their own proprietary specialty pharmacies. In the past few years, independent specialty pharmacies have seen an increasing incidence of PBMs terminating network applications or imposing excessive accreditation requirements and

abusive audits. Moreover, with little or no transparency, the PBM is free to funnel business to itself without regards to costs.

As mentioned earlier, PBMs negotiate rebates with manufacturers and typically claim that they pass along approximately 90% of these rebates to plan sponsors. However, this hinges on what is considered a "rebate." Rebate agreements between PBMs and manufacturers are considered "proprietary" and are not shared with plan sponsors. Also, many contracts allow PBMs to essentially "relabel" rebates. In this way rebate amounts can be "reclassified" as "formulary management fees," "healthcare data fees" or a variety of other creative monikers. As a result, even in a contract in which the PBM is required to pass along all rebates—these reclassified amounts are not included.

One additional point to mention on the topic of PBM contracts with plan sponsors is the issue of audit rights. PBMs have been relatively successful in putting into place certain "roadblocks" or phrases into contracts with PBM clients that prevent those PBM customers from conducting a meaningful audit. Some of these include vesting the PBM with "veto power" over certain auditors, limiting what information an auditor can review (citing proprietary information or trade secrets), restricting an auditor from sharing their findings or information with the plan sponsor/employer or prohibiting the auditor from copying any information or data that the auditor needs to review. In other words, effectively forcing the auditor to simply review paper records on-site at the PBM headquarters—and take notes. Once again, the lack of transparency does little to help customers or deter collusion, but rather is used for the financial advantage of PBMs.

PBM CONFLICTS OF INTEREST

The "big three" PBMs—Express Scripts, CVS Caremark and OptumRx control between 75-80 percent of the market, Each of these companies own mail order pharmacies and specialty pharmacies. PBMs also contract with all other retail pharmacies to form pharmacy networks that are direct competitors to

the PBM-owned pharmacies. Ultimately the PBMs set the reimbursement amounts for the retail pharmacies as well as the terms of engagement. PBMs also routinely audit retail pharmacies and through this process have access to purchasing records and invoices. In addition, CVS Caremark is a combination of a PBM and one of the largest retail pharmacy chains in the nation. This vertical integration that resulted from a 2007 merger reviewed by the FTC has only further muddied the water and afforded CVS an anticompetitive advantage. Case in point, prior to the 2007 merger of CVS and Caremark, 12% of CVS retail prescription revenue came from the Caremark PBM. By 2014, that share had tripled to 35%.[1] Since the approval of this merger, NCPA is aware of widespread CVS Caremark outreach to consumers urging them to utilize CVS pharmacies and the consumer contact information in these cases was derived from claims data processed by the Caremark PBM. Recently, NCPA has been made aware of widespread and pervasive CVS Caremark pharmacy reimbursement cuts in Medicaid managed care and commercial plans. There has also been a corresponding uptick in CVS Caremark outreach to the affected pharmacies inviting the pharmacy owners to "talk about your exit strategy," and inquiring whether the owner would "like to know what your store is worth?" These examples clearly illustrate the inherent conflicts of interest that arise when a vertically integrated entity is operating in the marketplace as both a reimburser (to independent pharmacies) and also as a competitor. Many times vertical integrations are touted as having the potential to provide tangible benefits to consumers; however, these examples illustrate the need for greater oversight into the grave conflicts of interest that are often created.

SUGGESTIONS FOR POSSIBLE POLICY RECOMMENDATIONS

1. FTC TO SUPPORT DOL 2014 RECOMMENDATION TO EXTEND REQUIREMENTS OF ERISA SECTION 408(b)(2) to ERISA HEALTH PLANS (PBMs must disclose all direct and indirect compensation to ERISA plans to determine if such compensation is "reasonable.")

[1] https://qz.com/636823/big-pharmacies-are-dismantling-the-industry-that-keeps-us-drug-costs-even-sort-of-under-control/

In 2014 the ERISA Advisory Council of the Department of Labor held a series of hearings on the topic of PBM Compensation and Fee Disclosure. In this context, the ERISA Advisory Council was considering extending the requirements of ERISA Section 408(b)(2) to employee welfare benefit plans (health plans). This section prohibits a "party in interest" from furnishing goods, services or facilities to an ERISA plan. There is an exception to this prohibition as long as the compensation is "reasonable." The Advisory Council recommended extending the "party in interest" prohibition to employee welfare benefit plans. This would require PBMs to disclose all direct and indirect compensation to ERISA plans to evaluate whether the compensation to PBMs and downstream pharmacies-including PBM-owned mail order pharmacies-and other subcontractors is reasonable.[2] The Advisory Council also recommended that the DOL consider issuing guidance to assist plan sponsors in determining whether to and how to conduct a PBM audit of direct and indirect compensation.

2. FTC TO COLLABORATE WITH DOL ON STANDARDIZED DEFINITIONS OF "BRAND," "GENERIC," "SPECIALTY," REBATE,"

3. FTC TO SUPPORT TRANSPARENCY EFFORTS SURROUNDING PBM "MAXIMUM ALLOWABLE COST" LISTS.

Currently there is no publicly available pricing benchmark for generic drugs. Instead, PBMs have proprietary "MAC" lists by which they use (different ones) to both reimburse pharmacies and bill plan sponsors. This system stands in stark contrast to the publicly available pricing benchmarks that exist for brand drugs. These MAC lists were initially developed to motivate pharmacies to seek out the "best" price for medications. However, this system does not work without some degree of transparency. Pharmacies have no idea what sources these MAC prices are based on and may not have access to these

[2] https://www.dol.gov/sites/default/files/ebsa/about-ebsa/about-us/erisa-advisory-council/2014ACreport1.pdf

prices depending on their geographic location and/or size. Due to this flawed system, many pharmacies are forced to dispense many medications at a loss.

4. FTC TO CONSIDER ADDITIONAL SCRUTINY OF INHERENT PBM CONFLICTS OF INTEREST THAT ARISE WHEN THE PBM IS OPERATING BOTH AS REIMBURSER AND COMPETITOR IN THE MARKETPLACE.

PBMs' inherent conflicts of interest in the healthcare marketplace warrant further scrutiny. For example, PBMs often contract with community pharmacies while also owning proprietary mail order and/or specialty pharmacies that compete with retail pharmacies. PBMs regularly design plans, including plans with preferred networks, that require or incentivize patients to use the PBM-owned pharmacy option over a retail pharmacy.

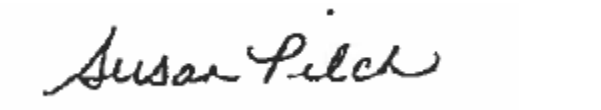
Moreover, when a PBM contracts with a retail pharmacy, PBMs have wide latitude in setting requirements for a pharmacy to be included in a network: the PBM determines how much the pharmacy will be reimbursed, which drugs will be covered, the day supply that the pharmacy can dispense, the patient co-pay, and many other factors. Many PBMs set unrealistic requirements such as requiring pharmacies to have drive-thru windows and having a pharmacist on call 24 hours a day. If a pharmacy cannot meet these unrealistic requirements, plans will exclude retail pharmacies from their networks. When PBMs own mail order or specialty pharmacies, PBMs utilize such road blocks to steer patients to the PBM-owned pharmacies.

Specifically, in the specialty pharmacy space, due to the lack of an industry-wide definition of a specialty drug, PBMs arbitrarily define high-cost drugs as "specialty drugs' and encourage or require that beneficiaries fill these prescriptions at PBM-owned or affiliated specialty pharmacies.

CONCLUSION

NCPA greatly appreciates the opportunity to share with you our comments and suggestions. If you have any questions, please contact Susan Pilch, Vice President of Policy and Regulatory Affairs, susan.pilch@ncpanet.org.

Sincerely,



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