Statement for the Record: The National Community Pharmacists Association (NCPA)

United States House of Representatives Energy and Commerce Committee Subcommittee

on Health

Hearing: "Examining the Drug Supply Chain"

December 13, 2017

Chairman Burgess, Ranking Member Green and Members of the Subcommittee:

Thank you for conducting this hearing on the pharmaceutical supply chain and how the delivery

system may contribute to the rising costs of prescription medications. In this statement, NCPA

would like to present our thoughts on the cost savings that can be realized by fully utilizing the

services of the pharmacist and also how we believe an intermediary party—Pharmacy Benefit

Manager (PBM) "middlemen"— in the supply chain are increasing complexity and contributing

to escalating drug costs. NCPA represents America's community pharmacists, including the

owners of more than 22,000 independent community pharmacies. Together they represent an

\$80 billion health care marketplace and employ more than 250,000 individuals on a full or part-

time basis.

More than any other segment of the pharmacy industry, independent pharmacies are often

located in the underserved and rural areas that are home to many Medicare beneficiaries. In fact,

independent pharmacies represent 52 percent of all rural retail pharmacies and there are over

1,800 independent community pharmacies operating as the only retail pharmacy within their

rural communities. Pharmacists have more medication-related education and training than any

other health care professional. Pharmacists can and do assist patients in optimizing the impact of

medications and decreasing patients' costs by providing services focused on safe and appropriate

1

medication use. For example, pharmacists provide medication management services, which are especially important for patients who have complex care plans, take multiple drugs, or have chronic conditions. Additionally, to address hospital readmissions, pharmacists help patients transition between care settings. Pharmacists are the most accessible health care professional but unfortunately, patients do not always have access to pharmacies that are closest to them because certain community pharmacies are excluded from preferred pharmacy networks by Pharmacy Benefit Managers ("PBMs"). Finally, pharmacists do not play a role in determining a patient's financial responsibility for prescription medications that they access through any prescription drug coverage. Ultimately, these amounts are determined by the insurer and the pharmacy benefits manager.

Overly Concentrated and Largely Unregulated PBM Marketplace

Three large companies lead the PBM market – Express Scripts, OptumRx and CVS Caremark – and these three companies collect more than \$200 billion a year to manage prescription services for insurance carriers covering 180 million Americans and government programs servicing approximately 110 million more. In addition, the largest PBM has increased its profit peradjusted prescription 500 percent since 2003. Since their inception, PBMs have morphed from claims adjudicators into little known and largely unregulated corporate giants that exploit their strategic position at the "middle" of nearly all drug transactions in the U.S. to extract profits from the upstream and downstream participants in the drug supply chain while providing questionable value to the ultimate consumer. PBMs are also heavily involved in and reap enormous profits

_

¹ How 'price cutting' middlemen are making crucial drugs vastly more expensive, available at http://www.latimes.com/business/hilzik/la-fi-hiltzik-pbm-drugs-20170611-story.html.

² Investor's Business Daily, Nov. 21, 2016, *available at http://www.investors.com/politics/commentary/a-sick-calculation-about-prescription-drugs/*.

from their involvement in federally supported or subsidized health care programs, like Medicare and Medicaid.

Current Lack of Transparency Regarding PBM Retained Rebates and "Spread" Profits

PBMs serve as the "middlemen" in most of all prescription drug transactions in the United States. They can leverage the number of beneficiaries in a particular plan to negotiate lucrative rebates from pharmaceutical manufacturers. They also formulate pharmacy provider networks that will supply or dispense these drugs to the plans' beneficiaries and in turn, charge the plan sponsor for these products. What most plan sponsors and consumers alike do not realize is that PBMs extract "spread" profits from both activities. PBMs typically claim they pass along approximately 90 percent of these manufacturer 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. Even in a contract in which the PBM is required to pass along all rebates, these reclassified amounts are not included.

It is also through these activities that PBMs wield immense power in influencing precisely what prescription drug products will be considered "on formulary" or that will be covered by a specific health plan. Typically, the actual drug products selected are chosen by the PBM to garner the greatest amount of rebate dollars. In addition, this "rebate game" has attracted a great deal of attention lately and it has come to light that the proliferation of these rebates is causing drug manufacturers to offset their payments to PBMs by raising the list prices of medications.

This dynamic is also extremely troubling considering the fact that in today's health care marketplace – in which many consumers receive prescription drug coverage under high-deductible plans— patient cost-sharing amounts for medications are based off these artificially inflated "list prices." Patient cost-sharing is a percent of the 'invoice' or retail price, not the net or rebated price. The Center for Medicine in the Public Interest confirmed this dynamic and specifically provided that rebates as percent of total price growth have increased ten-fold since 2011.³

In addition, the amount that the PBM reimburses a pharmacy for dispensing a drug is not the same amount that the PBM "charges" the plan for the same drug. The PBM "marks up" the cost, charging the plan more than the pharmacy is reimbursed, keeping the difference as pure profit. It is precisely these hidden spread amounts that should be disclosed.

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.

_

³ Robert Goldberg, *Drug Costs Driven by Rebates*, Center for Medicine in the Public Interest, *available at* http://bionj.org/wp-content/uploads/2015/11/drug-costs-driven-by-rebates.pdf.

Cost Savings to Health Plan Sponsors Could be Realized with Increased PBM

Transparency

The vast sums of money that PBMs are making by virtue of the drug spend of a particular plan should not be "proprietary" information on the part of the PBM. Instead, this information should belong to the plan. These disclosures could easily be protected by confidentiality agreements to address possible PBM concerns about such information weakening their negotiating stance with manufacturers. If plan sponsors have a clearer picture about the amount of money that is being made by their vendor by handling the plan's business, this may provide them with a greater ability to negotiate more competitive contracts in the first place.

Lack of Transparency in Generic Drug Reimbursement

In today's marketplace, generic drugs currently comprise approximately 86 percent of all prescriptions dispensed in the United States. ⁴ Given this fact, it is somewhat surprising that there is no standardized method for determining how pharmacies are reimbursed for generic drugs. PBMs create and maintain "Maximum Allowable Cost" or MAC lists that set the upper limit or maximum amount that a PBM/plan will pay for most generic drugs. Pharmacies are not provided any insight into how drug products are selected to be put onto this list or how exactly these prices are determined or updated. In short, contracted pharmacies have zero insight or transparency into the MAC process and sign contracts without having any idea of the rate at which they will be reimbursed for most of the prescriptions they fill. In response to PBM secrecy surrounding the creation and maintenance of these lists, at least twenty-six states have enacted

⁴ PhRMA, *The Reality of Prescription Medicine Costs in Three Charts*; May 27, 2014, *available at* http://www.phrma.org.catalyst.the-reality-of-prescription-medicine-costs-in-three-charts.

legislation to try to compel greater transparency into this system. The PBM industry in general has vigorously opposed these efforts and in fact is currently engaged in litigation with several individual states that have sought to compel compliance.

PBM Industry Largely Unregulated

Given the immense market influence that PBMs exert, one would expect these entities to be subject to the same type of comprehensive regulation that is currently required of commercial health insurers. However, PBMs are not subject to industry-wide regulation like what is generally required of commercial health insurers. There are no federal laws or regulations that are specific to the PBM industry. Instead, PBMs face a patchwork of regulations at the state level that are designed to curtail some of the more onerous PBM business practices such as abusive PBM audits of pharmacies and requirements related to timely MAC updates. However, even in states that have been able to pass these limited reforms, PBMs typically resist complying and have recently filed lawsuits against states.

Explosion of Pharmacy "DIR fees" in the Medicare Part D program are Increasing Costs to Consumers and the Medicare Program

Pharmacy direct and indirect remuneration ("DIR") fees are effectively clawback fees assessed on pharmacies retroactively months later, rather than deducted from claims on a real-time basis at the point-of-sale. Earlier this year CMS identified several concerns resulting from the rapid growth in pharmacy DIR fees⁵. First, beneficiaries face higher cost-sharing for drugs and are accelerated into the coverage gap or "donut hole" phase of their benefit. Second, more

⁵ CMS, *Medicare Part D – Direct and Indirect Remuneration, available at* https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html.

beneficiaries reach the catastrophic phase of the benefit, for which CMS incurs approximately 80 percent of the cost (HHS Office of Inspector General has noted⁶ that these catastrophic costs have tripled in recent years - from \$10 billion in 2010 to \$33 billion in 2015 – driven by pharmacy DIR fees). Third, liability for Part D costs is increasingly being shifted from Part D plan sponsors to CMS.

These findings were reinforced and bolstered by a report earlier this year by a leading actuarial firm commissioned by NCPA.⁷ In addition, MedPAC recently warned⁸ that, because of DIR, the gap between gross and net drug prices has grown 20 percent annually from 2010-2015 and that "plan incentives [are] not aligned with beneficiary and Medicare."

By utilizing tactics such as pharmacy DIR fees, the Part D plan sponsor or its PBM often receives additional compensation after the point-of-sale that serves to change the final cost of the drug for the payer, or the price paid to the pharmacy, for the drug.

The point-of-sale price/"negotiated price" recorded on Prescription Drug Event ("PDE") records is extremely significant. It is used to calculate beneficiary cost-sharing and to adjudicate the Part D benefit. Any fees or payment that are made after the point-of-sale are not reflected in the negotiated price but rather are reported to CMS separately.

⁶ HHS Office of Inspector General, *High-Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage*, *available at* https://oig.hhs.gov/oei/reports/oei-02-16-00270.asp.

⁷ The Impacts of Prescription Drug Direct and Indirect Remuneration under Medicare Part D, Feb. 2017.

⁸ Payment and plan incentives in Part D, April 7, 2017.

Many beneficiaries and caregivers rely on the online Medicare Plan Finder to evaluate and choose a Part D plan. However, the data displayed on Medicare Plan Finder are based on point-of-sale prices. The vast proliferation of DIR and post point-of-sale price concessions have rendered this drug price information grossly inaccurate.

Fortunately, CMS is acutely aware of DIR fees and their impact on Part D beneficiary and program costs. In the recently released Medicare proposed rule, "Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program," CMS explicitly states they are considering requiring all price concessions from pharmacies be reflected in the negotiated price that is made available at the point-of-sale and reported to CMS on a PDE record, even when such concessions are contingent upon performance by the pharmacy. NCPA strongly supports this approach. It would give independent community pharmacies greater predictability about their net reimbursement rates so they can make more informed operational decisions. In addition, it would not preclude any pay-for-performance arrangements between the Part D Plan/PBM and the pharmacy. Contrary to what the PBM industry has stated about this approach, CMS estimates that reflecting all pharmacy price concessions at the point-of-sale would result in significant beneficiary savings in cost sharing (at the pharmacy counter) as well as an overall savings (taking into account both premium amount and cost sharing amounts) over ten years.

Conclusion

In conclusion, the prescription drug marketplace continues to grow at an alarming pace. Large mergers continue to be announced every day while at the same time healthcare costs – and particularly prescription drug costs – are at an all-time high. The current business climate seems

to be one in which market power is increasingly concentrated in an ever-shrinking number of corporate entities. The overly concentrated and largely unregulated PBM industry exerts immense influence over how prescription drugs are accessed by the majority of Americans. Given the fact that the federal government is the largest single payer of health care in the United States,⁹ it makes financial sense for Congress to demand increased transparency into this aspect of the prescription drug marketplace in order to identify potential savings. In addition, Congress could enact common-sense legislation to address the proliferation of PBM-generated pharmacy "DIR" fees to lower out-of-pocket costs to Part D beneficiaries and reduce federal government Medicare Part D spending.

-

⁹ Troy, Tevi D., *How the Government As a Payer Shapes the Health Care Marketplace*, American Health Policy Institute, 2015.