US FDA AND STAKEHOLDER WORK PRODUCT:
Expert Consideration Summary Proposals for Lowering Prescription Drug Pricing While Improving Physician and Pharmacy Quality of Care

September 14, 2020

Dr. Peter Navarro
The White House
1600 Pennsylvania Avenue
Washington, DC 20500

Dear Dr. Navarro,

We appreciate the opportunity to present how pharmacy benefit managers (PBMs) drive up prescription drug prices for U.S. consumers and the federal government. Per our conversation with Ms. Miller and Dr. Hatfield, we respectfully submit the following data for your review and consideration. These recommendations represent the sentiment of more than 2,000 independent pharmacists. These data and recommendations are the culmination of more than a decade of thought, insight, and experience by over 10,000 experts, stakeholders and front-line health care providers who have dedicated their lives to the economics and practice of patient care.

A scant few companies have oligarchical ownership and authority over the majority of U.S. healthcare providers, payers, and pharmacies. Three PBMs - CVS Caremark, Express Scripts, and OptumRx - control an estimated 85% of the pharmacy benefits market. Misaligned incentives allow these unregulated entities to exploit legal loopholes at both the federal and state levels resulting in high prescription drug prices. **The annual revenues of the largest PBMs far outpace those of the largest drug manufacturers.** Two of the "Big 3" PBMs – CVS Caremark and OptumRx - belong to companies ranked ***in the top 10 of the Fortune 500 List***. The third, Express Scripts, a subsidiary of Cigna, ranks slightly behind at number 13.[1] **Although they claim otherwise, PBMs are <u>the true arbiters</u> of drug prices.**

<u>STAGE 1 CONSDIERATIONS</u>: PROTECTING PATIENTS AND PROVIDERS WITH CLEAR REMBURSMENT AND CARE-FOCUSED CONTRACTING REQUIREMENTS

1. Eliminate "safe harbor" protections for rebate kickbacks exchanged between PBMs and drug manufacturers. Rebate kickbacks result in higher drug prices and incentivize PBMs to engage in self-dealing and patient steering to PBM-owned pharmacies.
2. Create nationwide "Any Willing Provider" (AWP) laws that **mandate fair, standardized, and transparent contracting across state lines and prohibit steering to affiliate pharmacies**.
3. Bar PBMs from using profit-motivated, anti-patient delay tactics (e.g. prior authorization and "fail first"/step therapy) that disrupt patient care and override physician authority.
4. Require PBMs to be pharmacy benefits plan administrators (PBAs) operating strictly as pharmacy benefits claims processors and not plan designers or drug price "negotiators".

[1] Fortune 500 2020 https://fortune.com/fortune500/

STAGE 2 CONSIDERATIONS: PROTECTING SMALL BUSINESS PHARMACY PROVIDERS BY ELIMINATING HIDDEN FEES AND FORCING TRANSPARENCY

1. End Direct and Indirect Remuneration (DIR) fees, an anti-competitive practice in which PBMs take back thousands of dollars in drug reimbursements without notice or explanation, not only driving up patient costs at the point of sale, but leaving U.S. pharmacies scrambling and under tremendous financial stress and hardship.
2. Require PBMs to reimburse pharmacies at CMS' National Average Drug Acquisition Cost (NADAC) plus a professional dispensing fee for all health plans and prohibit the practice of tying pharmacy reimbursement to patient health outcomes.
3. Ban PBMs from charging pharmacies miscellaneous fees; conducting abusive audits with substantial punitive fines; or enacting other schemes designed to derive revenue from pharmacies, since pharmacies must be in the PBM network to receive patients.
4. Lobby Congress to allow FDA oversight of large prescription mail order facilities, replacing state boards of pharmacy whose current authority over such facilities is outdated, feckless and administered by appointees who may or may not have a pharmacy background or credentials.

STAGE 3 CONSIDERATIONS: EMPOWER THE FEDERAL GOVERNMENT AND STATES TO REIN IN ABUSIVE PBM PRACTICES IN THE COMMERCIAL MARKET

Nothing less than the full dismantling of the highly vertically integrated and oligarchical PBM system will reduce drug prices and restore the healthcare free market. While no one wants more bureaucracy, we believe with proper regulation of PBMs, American consumers, small businesses and taxpayers will see lower drug costs; higher quality of care; and better patient outcomes. The introduction of transparency and oversight will allow the U.S. to see a drop in the annual but unnecessary $300 billion spent on medical costs, often the result of drug plan coverage failures, plan misinformation, and other barriers to care created by PBMs.

Thank you for the opportunity to share our recommendations. We are available to meet with yourself as well as other White House advisors as well as other members to discuss our expert recommendations in further detail, answer questions and/or provide additional supporting documentation and data.

Respectfully,

/s/

Dr. David Gortler, PharmD, FCCP
Senior Advisor to the FDA Commissioner
U.S. Food and Drug Administration

/s/

Monique Whitney, MBA
Executive Director
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Attachments: ***A)*** *Signatures;* ***B)*** *Further Explanation;* ***C)*** *Supporting Documentation*

Attachment A
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Illinois Independent Pharmacy Coalition (representing 80 pharmacies)
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Georgia Pharmacy Association (685 independent pharmacies)
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Virginia Pharmacists Association, Academy of Independent Pharmacies (658 pharmacies)
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Allowing medical professionals - not actuaries and accountants - to make medical decisions will cut costs for consumers and taxpayers as medical costs associated with non-adherence and other medical emergencies arising from PBM "delay to pay" tactics are eliminated.

1. Require PBMs to be pharmacy benefits plan administrators (PBAs) operating strictly as pharmacy benefits claims processors and not plan designers or drug price "negotiators".

Currently PBMs are the metaphorical fox guarding the hen house. The recent slate of high-profile mergers that promised "firewall protections" for patient privacy have instead allowed insurance-owned, pharmacy-owning PBMs unfettered access to patient information, including the types of medications patients take, who prescribes them and where those prescriptions are filled. Additionally, PBM price dealings with manufacturers have stripped patients of the basic right to choose their medications, brand or generic.

Pharmacy benefits managers began as claims processors. Pharmacy and other health insurance claims processing is a service that is necessary and critical to the effectiveness of the U.S. healthcare system. **Pharmacy benefits administrators can and should follow the credit card processing business model**, processing claims on a fee basis that allows them to make a healthy profit. PBMs should NOT be allowed to design benefits plans, negotiate drug prices, market to patients, or own pharmacies.

The problem of PBM middlemen behaving as parasites on the prescription drug system has caught national attention in the media thanks to the efforts of the Trump Administration to stop the abuse. State level investigations have confirmed President Trump's observations of secret profiteering practices, including an explosive PBM investigation report published by the New York State Senate Committee on Investigations and Government Operations.[1]

The following is a partial list of practices that would end if PBMs were required to act in a transparent, administrative capacity:

- Reimbursement game playing and shell tactics, including the use of false PBM-invented reimbursement designations such as "Brand Effective Rate" and "Generic Effective Rate". PBMs use these designations to justify reimbursing pharmacies below drug acquisition cost while billing plan sponsors for the drug plus the PBM's markup

[1] **See Attachment C for New York Senate Report**

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- Creating fake organizations like the new "Group Purchasing Organization" (GPO). The GPO is a veneer for a practice PBMs have engaged in for the better part of decade: "buying" drugs at negotiated prices and "reselling" them to plan sponsors. This activity is a rebranding of price negotiation through rebates, invented to distract critics who have caught on to the PBM rebate game
- Creating sham designations such as "specialty" pharmacy, a term PBMs use to categorize and control sales of more expensive drugs for chronic disease states including HIV, multiple sclerosis, rheumatoid arthritis, diabetes, and cancer. PBMs require patients to use PBM-owned "specialty" pharmacies for expensive medications, all but ensuring they can exploit profit margins for maximum gain
- Marketing gimmicks for PBM self-dealing or steering patients to PBM-owned pharmacies and away from non-PBM owned pharmacies
- Opaque, covert, or non-disclosed spread pricing that adds $200 million or more to the cost of taxpayer funded healthcare programs
- Closed and "preferred" pharmacy networks that exclude pharmacies that could otherwise accept and fill a patient's prescription
- Inhospitable "take it or leave it" contracts that force smaller pharmacies to accept unfavorable terms and unsustainable business practices in exchange for access to patients
- Abusive pharmacy audits conducted by PBMs for the purpose of generating revenue in the form of stiff financial penalties
- Inaccurate, intentionally misleading letters and communications to patients for the purpose of scaring them into transferring or sending their prescriptions to PBM-owned pharmacies. Even when caught in the act, the financial penalties PBMs pay do not make up for the inconvenience to patients or loss to the patient's incumbent pharmacy
- Authorizing certain generics or brands and excluding others from a patient's formulary
- Disallowing the use of patient copay assistance for more expensive, "specialty" drugs to count toward the patient's deductible
- PBM-branded Medicare Part D prescription cards, currently an illegal practice but happening anyway and causing senior patients to think they must use a PBM-owned pharmacy

While this list is by no means exhaustive, it points to the urgent need for transparency in the prescription drug supply chain. PBMs vehemently oppose transparency, regulation, and oversight because transparency would disrupt the existing PBM business model and end profiteering.

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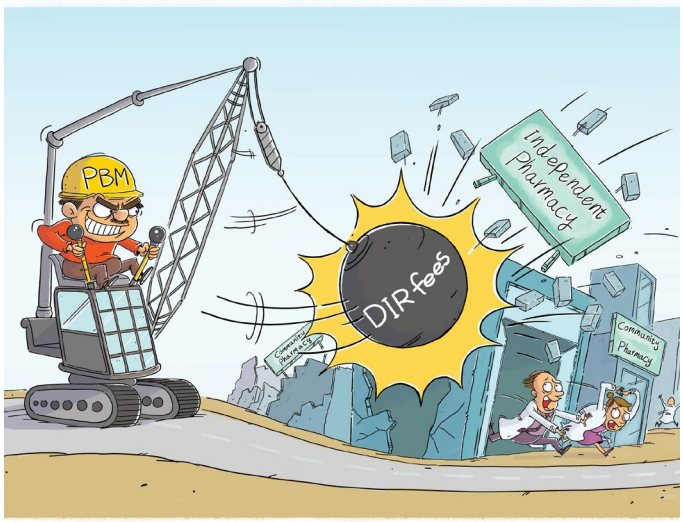
STAGE 2 CONSIDERATIONS: ADD TRANSPARENCY TO PRESCRIPTION DRUG PRICING, PROTECT PHARMACY PROVIDERS

1. **End Direct and Indirect Remuneration (DIR) fees, an anti-competitive practice in which PBMs take back thousands of dollars in drug reimbursements without notice or explanation, not only driving up patient costs at the point of sale but leaving U.S. pharmacies scrambling and under tremendous financial stress and hardship.**

   In 2018, the Trump Administration boldly proposed a rule that would eliminate retroactive DIR fees through HHS and CMS action. The rule was never finalized, but patients and pharmacies need DIR relief now in the name of reducing drug pricing for all Americans.

   PBMs claw back DIR fees from pharmacies in CMS' name, purportedly to lower Medicare Part D enrollee costs. **CMS does not allow, nor does it expressly prohibit, the collection of these fees,** yet PBMs collect more than $9 billion in DIR fees annually[2] while Medicare patient costs also increase. In the absence of transparency, it is unclear where the DIR fee clawbacks go or to whom they are actually paid.

   DIR fees are collected months after the original Medicare D pharmacy claim was adjudicated. Pharmacies have no way of knowing when, or in what amount, DIR fees will be clawed back from their business bank account. The seeming randomness of timing and amount make it extremely difficult for pharmacy owners to plan for inventory, labor, and other business decisions critical to the running of a business.



   This practice also obscures drug cost to the patient and the plan when fees are taken out retroactively but also on the front end. Transparency would allow patients, health plans and pharmacies to see upfront what fees are being taken by PBMs, when and why. Further, with transparency as the law of the land, all stakeholders – patients, plan payers, taxpayers and pharmacies – would have the benefit of complete information informing their choices and participation in the purchase and dispensing of prescription medication.

[2] **Pharmacy DIR Fees Hit Record of 9 Billion Annually, Drug Channels, February 2020**
https://www.drugchannels.net/2020/02/pharmacy-dir-fees-hit-record-9-billion.htm

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Between 2010 and 2017 DIR fees increased 45,000%[3], contributing to rapid closure of independent pharmacies and increasing the instance of "pharmacy deserts" in communities where accessible health care providers are most needed. Last year 4% of pharmacies closed nationwide; a recent survey revealed an estimated 58% of independent pharmacies are somewhat or very likely to close their doors over the next 2 years.[4]

PBMs justify the use of DIR fee clawbacks, tying DIR clawbacks to CMS' "stars" performance rating system, presumably with the intention of incentivizing pharmacies to go that extra mile toward helping patients meet favorable health outcomes. Still, CMS implemented the "5-star quality rating system" for consumers, to empower their choice of health plans by making quality data more transparent. *CMS' "stars" rating is intended for health plans, not pharmacies.* So, under a system of rewarding pharmacies for a health plan's performance measures, *how can a pharmacy come out ahead*?

Obviously, it is impossible. The ratings systems used by CVS Caremark, Express Scripts and OptumRx more or less show why.[5]

PBMs penalize pharmacies with higher DIR fees for outcomes beyond the pharmacy's control, e.g. patient adherence to medication; "grouping" pharmacies together such that one pharmacy's sub-par performance invalidates another's; or rating pharmacies based on the aggregate health profile of a community or region without regard to specific patients belonging to the pharmacy. PBMs have been known to downgrade a pharmacy for having a patient who, according to PBM data assembled by actuaries "should" be on a certain medication - a statin for example - but aren't because the patient has no need of a statin nor has the patient's doctor prescribed a statin.

DIR fees are also detrimental to Medicare patients. **DIR fees ultimately shift financial liability from the Part D sponsor to the patient, and finally to the federal government through Medicare's catastrophic coverage framework**.[6] Medicare patients first receive initial coverage, then move to the coverage gap ("donut hole") where they are responsible for paying a greater percentage of a drug's list price until they meet the coverage gap limit. Thereafter,

[3] 83 Fed. Reg. 62,152, 62,174, 62,191 (Nov. 30, 2018) - provided by Louisiana Independent Pharmacies Association (LIPA)

[4] Data provided by LIPA, See Attachment C: "Louisiana Trump DIR Brief" PDF

[5] See Attachment C: DIR Fee Performance Evaluation and Ratings System

[6] Frier Levitt, "Performance Based DIR Fees: A Rigged System with Disparate Effect on Specialty Pharmacies, Medicare Part Beneficiaries and the U.S. Healthcare System" via Community Oncology Alliance https://communityoncology.org/wp-content/uploads/2018/06/NASPWhitePaperonDIRFees.pdf