August 16, 2022

New York State Department of Financial Services
Pharmacy Benefits Bureau
Eamon Rock
1 Commerce Plaza
Albany, NY 12257

Re: PBM2022-04 - Request for Public Comments on the Practice of Patient-Steering by Pharmacy Benefit Managers in New York State

Dear Director Rock,

The National Community Pharmacists Association (NCPA) welcomes the opportunity to provide comments to the New York State Department of Financial Services, Pharmacy Benefits Bureau on the practice of patient-steering by Pharmacy Benefit Managers. NCPA is well positioned to comment on patient-steering, as NCPA can provide insights that both reflect our members' realities and that will guide the Bureau in identifying and proscribing the unlawful and anticompetitive practice of patient-steering.

NCPA represents the interest of America's community pharmacists, including the owners of more than 19,400 independent community pharmacies across the United States. Our 2,561 members in New York are small business owners who are among America's most accessible health care providers filling over 142 million prescriptions last year, impacting the lives of thousands of patients in your state.

NCPA's members and their patients continue to suffer from the anticompetitive effects of multiple horizontal and vertical mergers in the health care industry over the past 20 years. These mergers have resulted in a highly concentrated market structure that allows pharmacy benefit managers to "exercise undue market power."[1] Three vertically integrated companies now control access to more than 80%[2] of all prescriptions filled in the United States. They also have access to competitively sensitive information about their competitors. Each of these three companies possess market power in several relevant geographic markets.[3] The harm caused by the consolidation is not *only* to competitors who are squeezed out through exclusionary practices made possible by vertical integration, but also to competition and consumers. The White House Council of Economic Advisors reports that "[p]ricing in the pharmaceutical drug market suffers from high market concentration in the pharmaceutical distribution system and a lack of transparency."[4] As one New York government investigation found, with their unique position in the

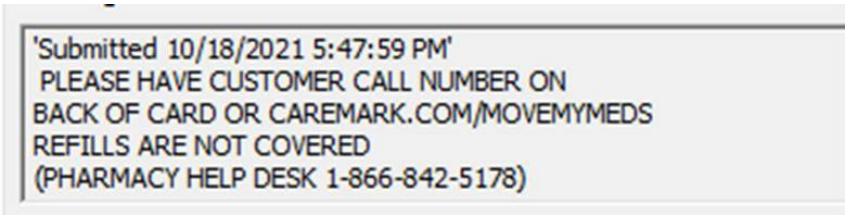
[1] The White House Council of Economic Advisers. (2018, February). Reforming Biopharmaceutical Pricing at Home and Abroad. Retrieved August 15, 2022, from https://trumpwhitehouse.archives.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.
[2] Fein, Adam. "The Top Pharmacy Benefit Managers of 2021: The Big Get Even Bigger." Drug Channels. April 5, 2022. https://www.drugchannels.net/2022/04/the-top-pharmacy-benefit-managers-of.html?m=1.
[3] Guardado, J., & Kane, C. (2021). *COMPETITION in HEALTH INSURANCE A comprehensive study of U.S. markets*. Competition in health insurance research. Retrieved August 15, 2022, from https://www.ama-assn.org/system/files/competition-health-insurance-us-markets.pdf.
[4] The White House Council of Economic Advisors, supra note 1 at 11.

pharmacy supply chain, "PBMs often employ controversial utilization and management tools to generate revenue for themselves in a way that is detrimental to health plan sponsors, patients, and pharmacies."[5]

PBM Patient-Steering Tools

PBMs have many tools they use to steer patients. Coercive and discriminatory copays are one such tool. PBMs set patient copays lower at PBM-affiliated pharmacies, including mail order pharmacies, and simultaneously set higher copays at pharmacies that compete with their affiliated pharmacies. These PBM created coercive copay structures are not only anticompetitive, they also greatly reduce patient choice as even a small copay increase may not be economically viable for a patient.

Another method includes a mandatory requirement to use a specific pharmacy. In practice, this can look like a refill "walk" (or steering) requirement after the patient is allowed to choose a pharmacy of their choice for the first fill or two. Below is a screenshot from an independent pharmacy's pharmacy management system. As you will see, the PBM requires the independent pharmacy to inform its patient that the patient must seek an alternative way of filling the patient's refills. Of course, the alternative method of refilling is through the PBM-affiliated pharmacy.



Failure to follow these exclusionary procedures often leads to audits and threats of termination of the pharmacy's network agreement. At the very least, PBMs force pharmacies to choose between filling the refill free of charge (real-time claims adjudication would prevent the independent pharmacy from submitting a claim) or let the patient go untreated until they find a PBM-affiliated alternative.

Mandatory PBM-affiliated pharmacy use is especially prevalent for "aberrant" or "specialty" drugs. Aberrant drug lists are not what they sound like. Originally used to identify drugs susceptible to patient misuse or substance use disorder, aberrant drug lists helped pharmacists identify drugs that required more careful screening. Now, PBMs use these lists to restrict pharmacy prescriptions for specialty drugs, or more expensive drugs, and steer that business to PBM-affiliated pharmacies.

PBMs utilize these lists as the basis for assigning maximum dispensing thresholds on independent pharmacies. One PBM's provider manual obligates independent pharmacies not to dispense beyond a 25% threshold (by dollar amount or number of claims for that PBM) of aberrant drugs. Therefore, if a patient presents with a prescription for a drug on the aberrant drug list, the pharmacist must guess whether that drug puts the pharmacy over the dollar threshold or number of claims threshold. If the prescription

[5] New York Senate Committee on Investigations and Government Operations, Final Investigative Report: Pharmacy Benefit Managers in New York, (May 31, 2019), available at https://www.nysenate.gov/sites/default/files/article/attachment/final_investigatory_report_pharmacy_benefit_managers_in_new_york.pdf.

gets the pharmacy close to this threshold, the pharmacy must choose between filling it or following the PBM's instructions to steer the patient to a PBM-affiliated pharmacy.[6] If the pharmacy chooses to fill the prescription and it places the pharmacy beyond the arbitrary 25% threshold, per the manual, the pharmacy could face a punitive audit, claim chargeback (i.e., no payment), or PBM-unilaterally-enforced "remedies" including contract termination. With those kinds of obstacles, patients are either steered to a different pharmacy, offered an alternative drug (if available and authorized by the prescriber), or in the worst-case scenario, left without access to any drug.

The PBMs further use these lists to limit who can be a "specialty pharmacy," -- a term PBMs arbitrarily define. Potentially, any independent pharmacy can be a specialty pharmacy, however, the PBMs make the sole determination as to whether they meet the opaque "criteria." If the PBMs do not determine the independent pharmacy meets PBM-established specialty pharmacy accreditation requirements, then the pharmacy cannot be part of the specialty pharmacy network. Such a process begs the question: when would a PBM with a downstream affiliated specialty pharmacy ever determine an independent pharmacy is worthy of such designation?

Insulin is the most notable case of PBMs steering patients to use different drugs to maximize their profits. For example, Express Scripts identified Semglee (an interchangeable biosimilar to Lantus) as a preferred formulary drug for 2022. However, coinciding with that formulary placement price jump, Express Scripts removed the brand referenced biologic drug, Lantus, from the formulary altogether. Mylan Pharmaceuticals discontinued the cheaper Semglee National Drug Code (NDC) and issued a new NDC. Express Scripts listed the new NDC for Semglee at the new-found, higher price. To offset this change, Express Scripts introduced insulin glargine, which is an unbranded biosimilar equivalent to Lantus, at the same time with a new NDC at the same price as the original Semglee -- $141 per box of pens. Unfortunately, Express Scripts did not place insulin glargine on the formulary. So, for a patient to get access to the less expensive insulin glargine, a patient would have to pay out of pocket and not have the payment count toward their annual deductible.

In these cases, PBMs claim that they secure large rebates from the manufacturer to bring the net cost of the product down to below the cost of the generic. Even if this was true (which would require complete transparency and 100% pass through of all monies that flow from a pharmaceutical manufacturer to a PBM), it does not negate the consumer harm that exists to patients when they are in the deductible phase and paying 100% of their medication costs. PBMs also will blame these formulary placements on plan sponsors, but plan sponsors, like others in this industry, are at the mercy of PBMs and their constant threats of rate hikes, all while making in record profits.[7]

[6] The Newsletter of Pharmacy Audit Assistance Services (PAAS) National. (February 2022). Newsline: Caremark® Expands "Aberrant" Language & Restricts Bulk Purchases.
[7] U.S. Health Insurance Industry Analysis Report. (n.d.). Retrieved August 5, 2022, from https://content.naic.org/sites/default/files/2021-Annual-Health-Insurance-Industry-Analysis-Report.pdf.

Other States Have Demonstrated the Negative Impact of PBM Patient Steering

In 2018, the Auditor of the State of Ohio produced a State Report on Ohio's Medicaid Managed Care Pharmacy Services that spoke to PBM conflicts of interest.[8] In it, the Auditor found discriminatory reimbursement because PBMs compensated their affiliated pharmacies at a higher rate than independent pharmacies. This discriminatory reimbursement occurs nationwide, based on evidence reviewed from Arkansas, Florida,[9] and Oklahoma. In fact, in February 2018, the Arkansas Pharmacists Association, joined by Arkansas Lt. Gov. Tim Griffin and almost half of the General Assembly, held a press conference unveiling data demonstrating that PBMs pay their affiliate pharmacies more than independent pharmacies.[10] The Arkansas data contained over 200 examples of discriminatory reimbursement. Of the top generic drug prescriptions, Arkansas found that the PBMs were paying themselves, on average, over $60 more per prescription than they were paying independent pharmacies. The PBM was steering patients to its affiliate so that it could pay itself more. Such anti-competitive behavior results in increased costs and harm to patients and should be investigated in New York too.

Proposed New York Rulemaking

The Request for Public Comments asks whether and how the Department should implement several proposed rules. Given the backdrop presented above, NCPA firmly believes the state must undertake rulemaking in the following areas.

1. **Prohibit Mandatory Pharmacy Use and Coercive Copay Structures**
   New York should adopt a rule restricting mandatory specified pharmacy use and discriminatory copay structures created to steer patients to PBM-affiliated pharmacies. A similar restriction should be placed on correspondence from vertically consolidated insurers/PBMs/GPOs/pharmacies that are used to steer patients to mail order pharmacies, or other specialized pharmacies, affiliated with that consolidated group. Similarly, the state should undertake rulemaking that would lift PBMs' anticompetitive restrictions on access to in-network pharmacies to give patients choice and to promote competition.

   Independent pharmacies provide a valuable resource to their community when independent pharmacies can deliver drugs to their patients if their patients are unable to come directly to the store. This is different from mail order delivery where the drugs can sit in delivery warehouses, trucks, etc., which can temper the efficacy of certain drugs. It is also an innovative competitive feature that the

[8] Yost, D. (2018, August 16). *OHIO'S MEDICAID MANAGED CARE PHARMACY SERVICES AUDITOR OF STATE REPORT*. Retrieved August 15, 2022, from https://audits.ohioauditor.gov/Reports/AuditReports/2018/Medicaid_Pharmacy_Services_2018_Franklin.pdf.
[9] Ally, A. J., Gaffner, A., Hong, J., Hunter, M., & Wang, M. (2020, December). *Pharmacy Benefit Manager Pricing Practices in Statewide Medicaid Managed Care Program*. Milliman Report Florida Agency for Health Care Administration. Retrieved August 15, 2022, from https://cdn.ymaws.com/www.floridapharmacy.org/resource/resmgr/docs_2021_legislative_session/milliman_report.pdf.
[10] Arkansas Pharmacists Association. (2018, February 23). *PBM Press Conference* [Video]. YouTube. https://m.youtube.com/watch?v=CDnFSOMAazA.

consolidated insurers/PBMs/GPOs/pharmacies cannot match because they are unable to provide the 1:1 pharmacist to patient care associated with this type of delivery. Limitations on such activity are anticompetitive and decrease innovations associated with such competition.

2. **Prohibit PBM Limitations on Community Pharmacy Bulk Purchasing**
   PBMs, and namely, CVS, recently began limiting quantities of drugs independent pharmacies can purchase from their wholesaler. There are two primary reasons independent pharmacies buy in bulk. First, they can buy at lower costs. Second, it guarantees they will have their patients' drugs on hand when it comes time to refill a prescription. PBMs limit bulk purchasing because they argue it is necessary from a fraud and audit perspective. However, the reality is bulk purchase limitations serve two purposes -- it forces the independent pharmacies to be less competitive because they have to buy at higher prices, and it forces independent pharmacies to steer patients to PBM affiliated pharmacies if they do not have access to the drugs. The state should restrict PBMs from placing such restrictions because it harms competition, and it could lead to a lack of access and higher prices for consumers within the state.

3. **Prohibit PBM Gatekeeping of Lifesaving Medications**
   Another way in which PBMs steer patients is to limit the number and types of medications that are available to patients. As described in the insulin example above, through formulary restrictions, PBMs force independent pharmacies to dispense higher cost drugs. This is problematic because when PBMs serve as gatekeepers to life saving medications for the purpose of padding profits, consumers suffer, and independent pharmacies are left explaining to their patients why. New York should propose a rule that would restrict this practice completely and instead require generics and bioequivalents to be available on formulary to New York consumers.

Patient steering is an anticompetitive practice that removes patient choice, prevents local health care providers from competing for patients' business, and increases costs for plan sponsors and consumers. It is important that the New York State Department of Financial Services Pharmacy Benefits Bureau's rules address these harms in a meaningful way that protects competition and consumers. Thank you for your time, and we are happy to answer any questions you have.

Sincerely,

Matthew Seiler

Matthew Seiler, General Counsel, NCPA