NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

December 7, 2017

Ms. Maureen K. Ohlhausen
Acting Chairman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington D.C., 20580

Dear Ms. Ohlhausen:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to comment on competition issues related to prescription drug markets. NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate 40,000 pharmacies, and NACDS' more than 100 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.2 million individuals, including 178,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 850 supplier partners and over 60 international members representing 21 countries. Please visit nacds.org.

We found the workshop hosted by the Federal Trade Commission (FTC) on November 8 to be a comprehensive and helpful conversation on this important issue. Our concerns are specific to Pharmacy Benefits Managers (PBMs). Specifically, we are submitting comments to address the questions posed by the FTC asking: "*What role do intermediaries, such as pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs) play in prescription drug pricing, consumer access, and quality? What are the benefits and costs of intermediaries in the pharmaceutical supply chain? Has consolidation affected price, access, or quality?*" We offer the following for your consideration as you analyze and put forth proposals related to competition in prescription drug markets.

We are concerned about what we perceive as opaque PBM interactions with pharmacies with respect to reimbursement and network design. While we realize there is a potential for PBMs to help patients and facilitate better patient care, we believe there are numerous improvements that can be made to how PBMs operate in the industry. As such, we would like to bring three areas to the FTC's attention for consideration: clear contracting practices, clear pricing methodologies, and the use of fees in the Medicare Part D Program.

1. Clear PBM Contracting Practices to Benefit Patients

PBMs use their significant market power and leverage to dictate contract terms to pharmacies. PBMs require pharmacies to sign one-sided, take-it-or-leave-it contracts to participate in PBMs' networks. Often, these contracts allow PBMs to make unilateral contract modifications. As noted by the National Community Pharmacy Association during the workshop, PBMs dictate reimbursement for pharmacies and what a pharmacy can charge a patient. In most cases, PBMs do not state clearly in their contracts the terms of pharmacy reimbursement. This often leads to

pharmacies dispensing drugs at a financial loss or risk losing many longtime patients. Just recently, OptumRx has come under scrutiny for employing gag clauses in their contracts with pharmacies, preventing pharmacists from informing patients that a certain medication is cheaper if paid for in cash. Such practices harm both the patient and the pharmacy and lead to a decrease in the quality of care.[1]

To combat these concerns, NACDS supports legislation and regulation that will protect patients and pharmacies from PBMs' aggressive practices and level the playing field with neighborhood pharmacies. We urge the FTC to consider the problems associated with unclear contracting practices when proffering proposals to help address issues around PBM practices.

2. Clear Pricing Methodologies

NACDS believes the pricing terms between a PBM and a pharmacy should be clear, objective, and consistent with both marketing and pricing practices as well as verifiable by the pharmacy. We support any legislation and regulation that would provide equity between PBMs and neighborhood pharmacies, such as including in contracts clearly defined drug pricing methodologies, routinely updating drug pricing, paying pharmacies promptly, providing sufficient detail (e.g., by populating the *Network Reimbursement ID field* on claims) to permit pharmacies to verify contract compliance, and allowing pharmacies to contest changes in their reimbursement. For your reference, NACDS uses the following model language to advocate for clear pricing methodologies at the state level:

(A) For the setting of prescription drug reimbursement benchmarks, including maximum allowable cost (MAC) lists, the PBM shall include in contracts with pharmacies information regarding which of the national compendia or other drug pricing source is used to obtain pricing data used in the calculation of the reimbursement amount and shall:

1. *Make price adjustments at least twice a month and shall provide pharmacies with prompt notification of any changes or additions made to reimbursement lists and rates at that time, except when a price for a drug changes by more than 100%. In such cases the price adjustment for that drug shall be made within three business days of the change in price; and*
2. *Provide a process for a pharmacy provider to comment on, contest, or appeal the prescription drug reimbursement amount, including a process to allow pharmacy providers to submit 200 claims per appeal, in an Excel file, containing all National Drug Codes (NDCs) within the Generic Product Identifier (GPI). The right to contest should be limited in duration and shall provide for retroactive payment in the event it is determined that the reimbursement amount has been calculated incorrectly.*
    i. *If the challenge is successful, the PBM shall make an adjustment in the drug price to the date of the originally challenged claim, and make the adjustment applicable to all similarly situated network pharmacy*

[1] Breslauer, Brenda, Anne Thompson, and Kenzi Abou-Sabe. "Could Your Health Insurance Be Costing You Money at the Pharmacy." NBC News. October 17, 2017. https://www.nbcnews.com/health/health-care/could-your-health-insurance-be-costing-you-money-pharmacy-n811171

providers, as determined by the managed care organization or pharmacy benefit manager, as appropriate.

ii. *A network pharmacy retains the right to collect or not collect additional appropriate co-payments from a patient after adjustments in the drug price after a successful challenge.*

3. *The PBM shall make all applicable price lists, including all changes in the price of drugs, available to network pharmacies upon request in a readily accessible and usable format, such as Excel, CSV, TXT, or Comma Delimited file which contains a complete list of the drug name, NDC, package size, per unit price, strength of drug, GPI and Generic Code Number (GCN). In the event there are multiple reimbursement lists under the same contract, the contract shall identify which lists are appropriately applicable.*

(B) A PBM shall also include in contracts with pharmacies a process for no less frequent than once a week updates to pharmacy product pricing files used to calculate prescription prices that will be used to reimburse pharmacies.

(C) A PBM shall disclose in contracts with pharmacies the types of fees to be imposed on the pharmacy, including any post adjudication fees and shall include a definition of such fees, a disclosure of how any fees will be calculated, and a schedule for when fees will be collected.

(D) A PBM shall report fees at the claim level to the pharmacy within 15 days after the collection of the fee.

(E) Generic Predictability: A PBM shall provide a contractual commitment to deliver a particular average reimbursement rate for generics. The average reimbursement rate for generics (e.g., "generic effective rate") shall be calculated using the actual amount paid to the pharmacy (such as through patient co-pays and PBM reimbursement), excluding the dispensing fee, and shall not be calculated solely according to the amount allowed by the plan and shall include all generics dispensed, regardless of whether they are subject to MAC pricing. The PBM shall disclose to the network pharmacy the methodology used in determining the generic effective rate.

(F) *A PBM may not charge a transaction fee, or any fees associated with processing or adjudicating a claim transaction that are not specified in the contract, for claims submissions provided in an electronic format by a healthcare provider.*

We believe that this language clarifies the responsibilities of the PBM and the rights of the pharmacy and is overall the best path to ensure quality patient care.

3. Use of Fees in the Part D Medicare Program

NACDS supports government wide efforts to investigate ways to keep healthcare affordable while at the same time maintaining patient access and health. One area we believe should be explored further is the impact of direct and indirect remuneration (DIR) fees on the Medicare Part D program. Earlier this year, the Centers for Medicare and Medicaid Services (CMS) released a Fact Sheet showing that the use of DIR by Part D sponsors has been growing significantly in recent years and has led to an increase in beneficiary cost-sharing, resulting in the patient reaching the coverage gap and the catastrophic payment level faster, which in turn led to an increase in subsidy payments made by Medicare and an overall decrease in plan liability for total drug costs.

Driven in part by its findings, CMS addressed these concerns in a recently released wide-ranging Medicare Part D proposed rule. In the proposed rule, CMS states:

> *…because of the advantages that accrue to sponsors in terms of premiums (also an advantage for beneficiaries), the shifting of costs, and plan revenues, from the way rebates and other price concessions applied as DIR at the end of the coverage year are treated under the Part D payment methodology, sponsors may have distorted incentives as compared to what we intended in 2005.*[2]

CMS goes on to say that "under current rules, therefore, Part D sponsors may have weak incentives, and, in some cases even, no incentive, to lower prices at the point of sale or to choose lower net cost alternatives to high cost-highly rebated drugs when available."[3]

While not proposing any immediate regulatory changes to DIR, CMS is soliciting feedback on how it might most effectively design a policy requiring Part D sponsors to pass through to beneficiaries a share of the manufacturer rebates they receive at the point-of sale.

CMS is also seeking comments on how it might update the requirements governing the determination of negotiated prices to better reflect current pharmacy payment arrangements to ensure that the reported price at the point-of-sale includes all pharmacy price concessions.

We encourage the FTC to coordinate with CMS to as you explore solutions to address the concerns related to DIR. One way we believe this can be accomplished is by issuing guidance to increase transparency between Part D plans and pharmacies in the use of DIR fees, post-adjudication fees, and quality and performance-based network fees by prescription drug plans in the Medicare program.

Such guidance should address the need for:

- consistency in terminology applied to pharmacy reimbursement in the Medicare program for Part D plans and downstream entities, and
- consistency in disclosures to pharmacies, including:
  - how fees are defined,
  - how fees will be calculated,
  - the timing for fee collection, and
  - how fees will be reported to pharmacies at the claim level, thus allowing reconciliation of reimbursement.

NACDS is not seeking to regulate the types of fees plans can use, how or when plans can use fees, or the dollar amount for such fees. Rather, we are seeking guidance that would require clarity and consistency in how fees are used and applied.

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[2] Centers for Medicare & Medicaid Services (CMS), HHS. "Medicare program; 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." 82 *Federal Register* 56336; 56419.
[3] *Id.* at 56421

We strongly believe that increased transparency in the Medicare program will benefit both the participating pharmacies and beneficiaries alike.

Conclusion

Thank you for the opportunity to comment, and we look forward to working with you on these important issues.

Sincerely,

Kevin N. Nicholson, R.Ph., J.D.
Vice President
Public Policy and Regulatory Affairs