National Rural Health Association

Lina Khan
Chairperson
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, D.C. 20580

RE: Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers

Dear Chairperson Khan,

Thank you for soliciting comments on the business practices of Pharmacy Benefit Managers (PBM). The National Rural Health Association (NRHA) appreciates the Federal Trade Commission's (FTC) attention to this critical issue and its impact on rural independent pharmacies. NRHA members have voiced significant concerns about the anti-competitive business practices of PBMs and how they are threatening viability for independent rural pharmacies and patients they serve. From a rural patient perspective, PBM abuses lead to unsafe and/or delayed care, making it hard to access basic medications.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes every component of rural America's health care, including rural community hospitals, critical access hospitals, doctors, nurses, and patients. We provide leadership on rural health issues through advocacy, communications, education, and research.

As you know, PBMs serve as a third-party administrator of prescription drug programs for commercial health plans, self-insured employer plans, Medicare Part D plans, the Federal Employees Health Benefits Program, and state government employee plans. In this role, they hold considerable influence on U.S. health care and drug spending. In 2018, the top three PBMs controlled approximately 77 percent of the market.[1] Furthermore, the top PBMs frequently report revenues that exceeded those of the top pharmaceutical manufacturers. For example, Express Scripts reported revenue of $100 billion while Pfizer had revenues of $52 billion in 2017.[2] PBM profits and business tactics have increased and become more difficult to comply with in recent years, with the impact felt by pharmacies throughout our rural communities.

The impact of PBM rebates and fees on net drug prices to patients, employers, and other payers.

NRHA members are concerned by practices PBMs take through a process called Direct and Indirect Remuneration (DIR) fees. PBMs charge pharmacies hidden DIR fees outside of administration charges, covered in the disguise of quality. These DIR fees are often clawed back retroactively months after the sale, rather than deducted from claims on a real-time basis. **This reimbursement uncertainty has made it difficult for rural pharmacies to operate.** In recent years, the prevalence and percentage of gross drug costs that DIR fees make up have steadily increased. In 2010, for example, DIR fees accounted for 11.3

[1] Fein, A. J. (2019, May 29). *CVS, Express Scripts, and the evolution of the PBM business model*. Drug Channels. Retrieved April 18, 2022, from https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html

[2] Kevin A. Schulman, M. D. (2018, June 12). *The Evolving Pharmaceutical Benefits Market*. JAMA. Retrieved April 18, 2022, from https://jamanetwork.com/journals/jama/article-abstract/2678286

percent of drug costs but by 2015 they made up 17.2 percent of drug costs. While the percentage of drug costs is concerning, what is equally concerning is the prevalence of these fees. The Centers for Medicare and Medicaid Services (CMS) cites that the use of DIR fees has ballooned by 107,400 percent between 2010 and 2020 – a dramatic increase from the 45,000 percent growth that CMS reported between 2010 and 2017.[3]

According to the National Community Pharmacists Association, between 2010 and 2018, the number of independent pharmacies decreased from 23,064 stores in 2010 to 21,767 stores in 2018.[4] That is a decline of 1,297 stores, or roughly six percent. During a similar time period, from 2003 to 2018, the Rural Policy Research Institute found that 1,231 pharmacies in rural areas closed.[5] This left 630 rural communities without access to retail pharmacies by 2018. Recent data from the National Association of Chain Drug Stores (NACDS) shows the trend continuing to worsen. Between December 2017 and December 2020, they figure almost 2,200 pharmacies closed nationwide.[6] As you can see from the data above, **as the prevalence of DIR Fees ballooned between 2017 and 2020, so did pharmacy closures, particularly in rural areas.**

It is imperative that the FTC takes action to reduce drug prices, bring transparency to the system, and address DIR fees. **DIR fees are becoming increasingly common, and PBMs are hitting pharmacies with extremely high claw backs, like a surprise bill, that force pharmacies to provide drugs below cost, and jeopardize their solvency.** One NRHA member in Missouri reported that in recent weeks (April 2022), they saw two DIR fees totaling $40,000 clawed back from two years prior. In many rural communities, this DIR fee, taken back two years later, could be used to pay for additional staff and patient services. Instead, the PBM collects based on price decisions two years later, causing financial turmoil for the pharmacy.

While the DIR fees have significant impacts on the bottom lines of rural pharmacies, they also indirectly impact rural patients. According to NACDS, the amount that Medicare patients pay for a prescription drug is supposed to be based on the cost of the drug. However, payers often calculate drug prices without subtracting the dollars that are taken back from pharmacies. What this looks like in practice is inflated patient drug costs because the calculation is based on a figure that is higher than what the payer is really paying. **As a result, not only do patients pay higher amounts based on prices before claw backs, but these practices are limiting their options due to forced offerings from restricted drug formularies that may force patients to higher priced drugs.**

Of additional concern are that DIR fees are being imposed on 340B eligible drugs. As you know, rural health providers depend on the 340B Drug Pricing Program to expand medication access and other services to individuals, families, and other vulnerable populations. According to multiple NRHA members, PBMs are reducing reimbursement for drugs due to 340B status or coming back later for recoupment based on the lower 340B price. Further, PBMs frequently limit the product that pharmacies can purchase, either due to white bagging or formulary limitations, causing the rural pharmacy to reimbursement for services, as well as potential 340B savings associated with the program. The 340B Program was designed to help covered entities stretch scarce federal resources further. When these

[3] https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir
[4] https://ncpa.org/newsroom/news-releases/2021/05/27/pharmacy-coalition-praises-legislation-relieve-patients-and
[5] https://rupri.org/2018/10/17/rupri-research-on-rural-pharmacy-closures-featured-in-us-new-world-report/
[6] https://www.nacds.org/news/pharmacy-coalition-praises-legislation-to-relieve-patients-and-pharmacies-from-pharmacy-dir-fees/

resources are being recouped disproportionately, the opposite becomes true. **NRHA is seeing the vulnerable hospitals and pharmacies the 340B Program was implemented to help protect close at alarming rates, in part due to practices taken by PBMs.**

Rural pharmacies continue to close at a disproportionate rate. When these pharmacies close, patient options dwindle. Given the unique size of rural pharmacies, they're often the only outfit in town. When these pharmacies close, it creates access and transportation challenges for rural residents. **To ensure patients in rural communities have access to the services they need, it is imperative that the FTC takes a stand to limit the utilization of this harmful practice.** The explosion we have seen in DIR fee amounts and utilization is alarming, and it is impacting rural communities and their patients disproportionately. NRHA urges the FTC to take decisive action to limit the utilization of this harmful practice to ensure rural communities and their patients are not further harmed.

PBMs' use of methods to steer patients away from unaffiliated pharmacies and methods of distribution and toward PBM-affiliated specialty, mail-order, and retail pharmacies.

NRHA members are also concerned by practices PBMs have taken around 'white bagging.' According to the American Hospital Association (AHA), white bagging is the practice of disallowing a provider from procuring and managing the handling of a drug used in patient care. Instead, a third-party specialty pharmacy, often PBM-owned or -affiliated dispenses the drug and sends it to a hospital or physician office on a one-off basis. **This creates access concerns for patients, but also increases administrative issues and costs for pharmacies, particularly in rural areas.**

When PBMs begin limiting the handling of a drug, rural pharmacies are on the hook for additional work and administrative costs. For example, one member pharmacy told us that at any given point, they could be working with 20 different pharmacies to ensure drug access for 20 different individuals. This means the pharmacy staff has increased administrative burdens by having to keep receipts of the medication in additional storage. When the PBM requires the provider to utilize a third-party specialty pharmacy, they must buy all the equipment that comes with it. Then, the pharmacy staff is required to do all the patient management services and coordination without reimbursement associated. This creates significant concerns for rural pharmacies with NRHA members reporting 25 percent of their revenue gone due to white bagging practices, but all the work in getting access to medication for the patient remains given their remote states. In some urban and suburban areas, health systems are not allowing white bagging, requiring patients to travel to the affiliated specialty pharmacy. Unfortunately, in rural communities, there isn't an option. If the rural pharmacy doesn't comply, the patient may not have another option for access to the drugs and services they need.

NRHA is deeply concerned by the white bagging practices occurring nationwide. **Not only does it negatively impact rural pharmacies' ability to provide services, increase administrative workload, and financially impact them, but it also puts patient safety in jeopardy.** There are instances where drug doses for certain patients are dependent upon lab tests and other provider activities. White bagging policies hinder the ability of a provider to adequately adapt and change dosing as necessary. Further, shipping errors are common. When a third-party specialty pharmacist is tasked with sending appropriate medication and it is not properly filled, the process at the hospital or pharmacy becomes convoluted. Pharmacies are required to find a way to ensure the prescription is filled, spending additional money and resources, then working through the PBM or third-party specialty pharmacy to be reimbursed, if at all.

National Rural Health Association

NRHA urges the FTC to work to prohibit white bagging processes and the offer of non-negotiable contracts. Ultimately, what we're seeing in rural communities are pharmacies being forced to work with third-party specialty pharmacies, not being reimbursed, but doing the same amount of, if not more, work. Further, it jeopardizes care for patients. Pharmacies are often scrambling to ensure drugs are adequately dispensed to their patients, while PBMs continue dictating where drugs are dispensed from. These practices are dangerous, unhelpful, and further impact the bottom lines of fragile rural pharmacies. NRHA urges action to rein in these harmful practices.

NRHA appreciates the FTC for looking into this critical matter. Ensuring the stability of rural pharmacies and providers is critical to the rural way of life. If you have additional questions on this issue, please contact Josh Jorgensen (jjorgensen@ruralhealth.us).

Sincerely,

Alan Morgan
Chief Executive Officer
National Rural Health Association

RuralHealthWeb.org
50 F. St., N.W. Suite 520
Washington, DC 20001 | 202-639-0550