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May 23, 2022

Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Submitted electronically via regulations.gov

RE: [FTC-2022-0015-0001] Solicitation for Public Comments on the Business Practices of Pharmacy Benefit Managers and Their Impact on Independent Pharmacies and Consumers

Dear Commissioners,

On behalf of the 7,700 members of the American College Rheumatology (ACR), I write in response to the Federal Trade Commission's (FTC) solicitation for comments on the business practices of pharmacy benefit managers (PBMs) and their impact on our patients. The ACR appreciates the opportunity to elaborate, from the perspective of the rheumatology care team, on the impact of PBMs on our patients' ability to access medically necessary therapy.

Rheumatologists and rheumatology healthcare professionals provide ongoing care for patients, including Medicare beneficiaries, with complex chronic and acute conditions that require specialized expertise. We provide primarily non-procedure-based care to patients with severe, frequently life-threatening conditions that can be difficult to diagnose and treat, including rheumatoid arthritis and other forms of inflammatory arthritis, vasculitis, systemic lupus erythematosus, and other debilitating diseases. Rheumatologists and rheumatology professionals also work closely with physical and occupational therapists to maximize the ability of patients to achieve and maintain independence outside of long-term care facilities and other healthcare settings. Early and appropriate treatment by rheumatologists and rheumatology professionals can control disease activity, prevent or slow disease progression, improve patient outcomes, and reduce costly surgical and other interventional procedures. These improved outcomes enable our patients to continue to be more productive than they would have been without timely treatment.

PBMs were conceived as an intermediary to negotiate medication prices and maintain drug formularies while taking into consideration the benefits of the treatment and their market cost. Unfortunately, and largely due to perverse incentives, PBMs quickly became a significant contributor to the high drug prices that plague our healthcare system. Today, three PBMs manage 71% of prescription drugs in our healthcare system with no fiduciary responsibility to patients.[1]

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[1] *The role of pbms in managing drug costs, implications for a ... - KFF*. (n.d.). Retrieved May 10, 2022, from https://www.kff.org/wp-content/uploads/2013/01/the-role-of-pbms-in-managing-drug-costs-implications-for-a-medicare-drug-benefit.pdf

Furthermore, PBMs' remarkable control over the cost and access to prescription drugs is maintained by way of opaque practices in the absence of meaningful oversight or regulation. **We applaud the FTC for thoroughly examining the practices of PBMs and their direct and indirect impacts on formulary design, utilization management, cost to our patients and the healthcare system, and reduced access to medically necessary treatments.**

Below we provide comments on specific questions outlined in the solicitation for comment.

Impact of PBM rebates and fees on net drug prices to patients, employers, and other payers

Theoretically, PBMs should use purchasing power to negotiate fees and rebates with drug manufacturers and then pass those rebates to the pharmacy and patient. In practice, however, the PBMs retain these rebates to increase their profit margin, leaving other stakeholders to continue to pay high drug prices. A 2020 study by the USC Leonard D. Schaeffer Center for Health Policy and Economics showed a positive correlation between drug rebates and list prices. The study found that for every $1 increase in rebates, there was a $1.17 increase in the list price. This positive correlation is particularly notable for brand-name products that do not have a generic alternative. [2]

While net prices are more frequently discussed in the drug pricing conversation, it is important to highlight the role of increased list prices on the patient. Many health insurance companies now require a patient's cost-sharing responsibilities based on the list price. Increasing the list prices to create more favorable rebates and inclusion in PBM formularies excludes many patients from medically necessary therapy due to the high out-of-pocket costs which make the drugs prohibitively expensive.

Impact of PBM rebates and fees on formulary design and patients' ability to access prescribed medications without endangering their health, creating an unnecessary delay, or imposing administrative burdens for patients or prescribers

Ideally, formularies would be designed based on safety and clinical efficacy. However, they are currently designed to maximize rebates from drug manufacturers. PBMs populate formularies with drugs from manufacturers that offer the highest rebates, and PBMs keep the rebates to increase profit. Drugs with lesser rebates are usually excluded and not covered. Manufacturers therefore compete to increase rebates and ensure their products are on the formulary. However, they do not simply increase rebates; instead, manufacturers increase list prices which, in turn, allows for higher rebates. **Thus, competition in this market does not result in reduced prices for patients, but only serves to increase the rebate revenue that is captured by PBMs**. This dysfunctional market perversely incentivizes manufacturers and PBMs to increase drug prices forcing patients to shoulder the higher out-of-pocket expenses, take less effective treatments, or forgo medically necessary treatment entirely. This can often result in a patient who is doing well and effectively contributing to society on

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[2] Sood, N., Ribero, R., Ryan, M., & Nuys, K. V. (2022, April 7). *The association between drug rebates and list prices*. USC Schaeffer Center for Health Policy and Economics . Retrieved May 11, 2022, from https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/

a given therapy being forced to switch to a different drug, which may not allow the patient to be able to function as well and continue in the workforce.

As part of their role as benefits managers, PBMs also outline utilization management tools to control the use and cost of prescription drugs. Tools such as prior authorization and step therapy are used by payers to reduce spending by requiring permissions and fail-first policies that result in unnecessary delays in patients' access to treatment.

Prior authorizations are arduous, burdensome processes that delay patient care while creating an unnecessary administrative burden on the rheumatology care team and diverting time away from patient care. A recent AMA survey shows that 34% of surveyed physicians report that prior authorizations have contributed to severe adverse events.[3] Sadly, many of the required prior authorizations yield an approval following an arduous process. This is particularly true for chronic care medications which may continually undergo the prior authorization process. Patients suffering from rheumatic diseases rely on life-changing medications to allow for a good quality of life. As rheumatic diseases are chronic conditions, these treatments are needed continuously. Yet, despite their necessity and past prior authorization approvals, many physicians are required to submit prior authorizations for every refill. Patients are forced to wait for their treatments, negatively impacting their health and productivity.

As a result, physicians and their staff spend needless time managing these prior authorizations, time that they could more effectively devote to badly needed patient care. The AMA survey on prior authorization reports that 88% of physicians deem prior authorization a significant or extreme burden. As a result, many physicians have been compelled to employ dedicated staff to handle all required prior authorizations. [4]

Step therapy is another form of utilization management that hinders our patients' access to care. The fail-first requirements force patients to fail insurer-preferred treatments before allowing patients to access the treatments that the clinician initially prescribed. As rheumatologists and rheumatology professionals, it is our job to ensure that patients can access the right treatment at the right time. Unfortunately, step therapy significantly delays access to the most appropriate treatment while requiring our patients to unnecessarily suffer by taking less-effective medications that do not help manage their disease.

PBMs were developed to help manage the complex prescription drug space. However, they have developed into a revenue-driven entity with immense control over access to needed treatments for our patients with no fiduciary responsibility. If their practices remain unchecked, PBMs will continue to significantly influence the overall price of prescription drugs through formulary design and prevent access to care through unnecessary reliance on utilization management tools. The opaque

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[3] American Medical Association . (n.d.). *Ama Prior Authorization (PA) physician survey*. Prior authorization physician survey and progress report. Retrieved May 6, 2022, from https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

[4] American Medical Association . (n.d.). *Ama Prior Authorization (PA) physician survey*. Prior authorization physician survey and progress report. Retrieved May 6, 2022, from https://www.ama-assn.org/system/files/prior-authorization-survey.pdf

business practices of PBMs and their relationship with private payers are detrimental to efforts to curb the high cost of drugs. Without understanding and providing greater oversight of PBMs, our country will not be able to reform drug pricing effectively. We urge the FTC to thoroughly study PBM business practices to lead further discussions and policies to lower drug prices.

The ACR firmly believes that drug pricing reforms are necessary to ensure the health of our patients and the sustainability of our healthcare system. Therefore, we commend the FTC for soliciting comments on PBM practices' impact on the healthcare team and patients. We welcome the opportunity to be a resource as you consider further study of these entities. Please contact Amanda Grimm Wiegrefe, Director of Regulatory Affairs, at awiegrefe@rheumatology.org for additional clarification or questions.

Sincerely,

Kenneth G. Saag, MD, MSc
President, American College of Rheumatology