Alliance of Specialty Medicine

Sound Policy. Quality Care.

May 17, 2022

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

To Whom It May Concern:

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians and is deeply committed to improving access to specialty medical care through the advancement of sound health policy. We write to share feedback in response to the Federal Trade Commission's Request for Information (RFI) related to the pharmacy benefit manager (PBM) industry.

The questions posed by the RFI acknowledge the fact that the harms caused by horizontal and vertical consolidation in the PBM industry are not limited to the pharmacy community. Indeed, patients in need of expensive medications have not only seen community pharmacy access points disappear, but they have also become entirely commodified in the contracts between drug companies and PBMs.

The intense consolidation in the PBM industry over the last decade has helped create this situation. Three PBMs control almost 80% of U.S. prescriptions, a number that may be even greater when one accounts for the fact that smaller PBMs often contract services to "the Big Three." In effect, PBMs have become the primary gatekeepers to commercial pharmaceutical markets: a drug company must secure formulary access or forfeit meaningful uptake of its product.

This arrangement could benefit patients if the gatekeepers were working to their benefit, but the incentives inherent in the price concession system virtually ensure the opposite. Patients' cost-sharing is based on list prices, which *rise* in tandem with price concessions.[1] Additionally, patients – including stable patients – are steered to the product manufactured by the company that won that year's price concession contest. The price concessions are sufficient to reduce the list price by more than half on many medications.[2] That fact alone illustrates the deep disconnect in the system, since patients never see a commensurate 50% reduction in their out-of-pocket drug costs. In fact, very few patients report *any* reduction and are instead faced with increasing out-of-pocket costs every year. This is why the Office of the Inspector General finalized a rule to remove the safe harbor from antikickback law for

[1] *The Association Between Drug Rebates and List Prices*, Neeraj Sood, PhD, et al., University of Southern California, Leonard D. Schaeffer Center for Health Policy & Economics, finding that, "Drug rebates and list prices are positively correlated: On average, a $1 increase in rebates is associated with a $1.17 increase in list price."
[2] *Gross-to-Net Bubble Update: Net Prices Drop (Again) at Six Top Drugmakers*, Drug Channels.

rebates from drug companies to PBMs unless these rebates are passed through to patients. The Alliance supported that proposal and is eager for its implementation.

The price concession system by which formularies are designed results in bewildering scenarios:

- A $10,000 prostate cancer drug is covered, but its $400 generic is kept off formulary.[3]
- Three rheumatoid arthritis medications share the same mechanism of action, but one is priced at less than half of the other two. The cheapest option has only a 3% market share because it cannot gain formulary access.[4]
- A large health insurer/PBM sends stable patients a $500 cash card offer to switch medications to the one preferred by the insurer, absent any clinical reason to do so.[5]

These are but a few examples of the counterintuitive outcomes of the current drug pricing system. Meanwhile, utilization management has gotten increasingly aggressive, with physicians now spending $26.7 billion each year navigating these protocols.[6] The American Medical Association's annual survey on prior authorization found that, in 2021, 34% of physicians reported that prior authorization led to a serious adverse event for a patient, with 24% stating that prior authorization even led to a patient's hospitalization. These tactics are used to delay or deny all aspects of care, including needed surgical care. On the pharmaceutical side, the protocols seem driven by the need to minimize spending on non- or low-rebated drugs and maximize spending on drugs that are highly rebated or result in high "administrative fees" from the manufacturer.

The over-consolidation in this industry is not only horizontal, but also vertical: the big three insurers/PBMs have also begun acquiring physician practices, which places them in full control of the prescription down to where it originates. Vertical consolidation has intensified the already notorious opacity of the industry, since now almost every entity in the supply chain is affiliated. A recent investigation of the PBM industry by the PBM Accountability Project could not characterize almost 40% of PBMs' gross profits, despite an examination of all publicly available data, an extensive literature review, and a survey of industry insiders.[7]

Finally, patients in need of provider-administered medications are increasingly steered towards PBM-owned specialty pharmacies, which often require the patient to pay the full cost-sharing up front or the prescription will not be shipped. It also causes logistical nightmares for medical practices related to

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[3] "When the $10K brand name drug is more affordable than its $450 generic: How PBMs control the system" Zachary Brennan, *Endpoints News*, 02/18/22.
[4] "Formulary Exclusions Favor Rinvoq Use and Increase Costs" *American Rheumatology Network*, 05/15/20.
[5] "Cigna Dangles $500 to Persuade Patients to Switch Psoriasis Drugs" Allison Inserro, *American Journal of Managed Care*, 03/26/21.
[6] "Quantifying the Economic Burden of Drug Utilization Management on Payers, Manufacturers, Physicians, and Patients" Scott Howell, et al., *Health Affairs* vol. 40, no. 8.
[7] Understanding the Evolving Business Models and Revenue of Pharmacy Benefit Managers, PBM Accountability Project (2021).

inventory management and results in increased waste of expensive medications. This move to in-house specialty pharmacy is a direct result of vertical consolidation in the industry.

Untangling this system will be difficult, but with only limited information, it will be impossible. Thus, we urge the FTC to conduct a thorough study of the PBM industry and all of its contractual dealings with drug companies, as well as the arrangements that the big three PBMs enter into among their own affiliated entities. Above all, we urge you to consider whether the patient benefits from this system in the form of improved clinical care or lower out-of-pocket costs for prescriptions.

Should you have any questions or wish to schedule a meeting, please contact us at info@specialtydocs.org.

Sincerely,

American Academy of Facial Plastic & Reconstructive Surgery
American Academy of Otolaryngology – Head and Neck Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American College of Osteopathic Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
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