COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

CALLING ALL RHEUMATOLOGISTS:
Provide feedback to the Federal Trade Commission as it studies the impact of pharmacy benefit managers on drug pricing and patient access.

The Federal Trade Commission (FTC) is requesting feedback from stakeholders, including physicians, about pharmacy benefit managers (PBMs) and their impact on drug pricing and access to medication. If the provider and patient communities can help illustrate the access issues caused by PBMs, the FTC may move forward with a comprehensive review of the industry and recommend reforms to Congress.

This alert explains exactly what the FTC is asking and how you can help answer its questions. ***Make your voice heard: submit your comments to the FTC before the April 25 deadline!***

Unfamiliar with formularies or PBMs? For those new to the issue, find an overview at the end of this document explaining formulary design and the influence PBMs have on them.

What is the FTC asking?

The Federal Trade Commission (FTC) recently issued a request for comments on how the practices of PBMs affect drug pricing and patient access to medication. This solicitation requests feedback from stakeholders on several PBM-related issues, including the impact of price concessions on drug prices, formulary design, and patient access. The FTC is also interested in information about non-medical switching and PBM-created administrative burdens on patients and providers.

How can you help?

CSRO will submit a detailed comment letter on behalf of its members, and we urge rheumatologists across the country to file individual comments as well. Below, we've provided an outline with suggested content.

Once you've put together your comments, you can submit them **here**. You'll be able to either copy and paste your comments or attach them as a Word or PDF file, although *we recommend attaching them as a Word or PDF document to avoid the character limit* in the submission field supplied by the FTC. **Your submission will become part of a public docket, so please ensure patient confidentiality in the examples you provide.**

Comments can be submitted **any time before April 25, 2022**.

Draft Submission Outline

The below outline is organized along the issues being considered by the FTC. A few pointers:

- You do not have to answer every question. Even one well-answered question will help!
- Restating these talking points to be in your own voice is strongly encouraged – this outline is intended to provide ideas and context for your personalized statement.
- Specifically, **the *italicized text* highlights opportunities to share personal stories**. Individualized feedback will be the most useful to the FTC as it tries to quantify the effect on patients nationwide.
- Comments can be submitted via a field on the FTC's online form OR uploaded as a Word or PDF document. *Please note:* there is a 5,000 character limit for statements submitted via the online form, and if using the below outline in its entirety, it will exceed that limit.
    - If using the field on the form, consider limiting your comments to one or two issue areas with compelling personal examples.
    - It is recommended to upload your letter in a Word or PDF format, avoiding the limit entirely.

To submit your comments, click here, or copy and paste the below into your web browser: https://www.regulations.gov/commenton/FTC-2022-0015-0001

OPENING: My name is [*NAME*] and I am a practicing rheumatologist in [*STATE*].

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

TALKING POINTS:

- While PBMs collect price concessions (rebates and fees) there is **no transparency** as to where those concessions go. The big three PBMs now have **rebate aggregators, which enable them to "hide" rebates** from plan sponsors, legislators, and regulators. Despite price concessions of over 50% on many expensive medications, **patients are still forced to pay cost-sharing on the list price** (pre-price concession).
- We now have many biologics and targeted disease modifying agents, yet list prices are only rising. It seems as though competition to get on the formulary is actually *increasing* list prices of drugs.
- For example, an insulin biosimilar was recently deemed "interchangeable" by the FDA, yet only the highest priced biosimilar is available on most formularies.
- Research conducted at the University of Southern California found that, for every $1 increase in rebates, there is an associated $1.17 increase in list price. Since patients' cost-sharing is often based on the list price, this correlation has the effect of raising the financial burden on patients.
- *[If applicable, provide a few brief examples of insured patients who cannot afford their medication or who ration medication due to cost.]*

FTC INQUIRY: The impact of PBM rebates and fees on formulary design and patients' ability to access prescribed medications without endangering their health, creating unnecessary delay, or imposing administrative burdens for patients or prescribers.

TALKING POINTS:

- Price concessions drive formulary design, which in turn drives utilization management.
- *[Describe example of difficulty you and/or a patient encountered in accessing a medication you prescribed. Provide as much detail as possible on the type of difficulty: step therapy, delay tactics in the form of administrative burdens, etc. Describe negative consequences resulting from the delay or denial.]*
- *[Describe how many resources your practice dedicates to administrative burdens. For example, do you have a full-time staff person dedicated to helping patients access their medications? How many hours of your day are diverted to administrative barriers by insurers or their PBMs?]*

FTC INQUIRY: Whether patients are being forced to substitute different prescription drugs to maximize PBM rebates and fees.

TALKING POINTS:

- Insurers and their PBMs have become so aggressive in their attempts to switch patients that these tactics amount to coercion. For example, an insurer may allow a patient to continue on a medication as long as the patient pays a 50% coinsurance, which is a functional denial. Insurers also deploy ethically questionable incentives, such as contacting patients directly to offer $500 cash for switching medications.
- *[Describe example(s) of nonmedical switching. Have you had patients who were stable on their medication who were forced to switch by the insurance company? What was the outcome? From a clinical perspective, why is it bad to switch stable RA patients if there is no clinical reason to do so?]*

FTC INQUIRY: PBMs' policies and practices related to specialty drugs and pharmacies, including criteria for designating specialty drugs, reimbursements to specialty pharmacies, practices for encouraging the use of PBM-affiliated specialty pharmacies, and practices relating to dispensing high-cost specialty drugs over alternatives.

TALKING POINTS:

- In the commercial market, there is no single definition of "therapeutic class," so the PBM defines it for maximum financial benefit. Even terms defined in federal law such as "generic" and "brand" lack a standardized definition in PBM contracts.
- Now that PBMs are part of health insurance companies, they steer patients to sites of care that are owned by the "parent" company or to medications that are mandated to come from specialty pharmacies that they own.

- *[If applicable, provide example of medication being recategorized from one year to the next, or example of medication being categorized differently across plans.]*
- *[If you provide in-office infusion, have your patients experienced pressure from their insurers/PBMs to have medication delivered to the home to be brought in to your office for infusion? What are the risks of that approach?]*

FTC INQUIRY: Potential conflicts of interest and anticompetitive effects arising from horizontal and vertical consolidation of PBMs with insurance companies, specialty pharmacies, and providers.

TALKING POINTS:

- The PBM industry has **consolidated into just three entities** that now control over three quarters of the U.S. prescription drug market.[1] This consolidation is further exacerbated by vertical integration. **All of the three big PBMs are now owned by or own large insurance companies**. Now that large portions of the supply chain are consolidated under just three parent entities, contracts within each of the three amount to moving revenue among subsidiaries. **A payer who owns a PBM can no longer be considered the PBM's "customer."**
- Over-consolidation has also created immense concentration of market power in a single entity. That leaves patients, medical providers, independent pharmacies, and even drug companies on unequal footing in terms of negotiating power.
- *[If applicable, describe strong-arming tactics that you've experienced, such as "take-it-or-leave-it" reimbursement at the threat of being dropped from the network.]*

CLOSING PARAGRAPH/SOLUTION:

We need to center the ***patient*** as the consumer to be served by our drug supply chain. *[NOTE: this is the main message we hope to communicate to the FTC, as they currently view the insurer/payer as the consumer, NOT the patient.]*

In 2019, Dr. Madelaine Feldman suggested a way to accomplish this in a Healio piece entitled "Formulary Construction in America." I agree with the ideas shared in that article and urge the FTC to consider exploring some of these solutions to addressing the harmful impacts of PBMs on our drug supply chain.

- Dr. Feldman suggests that, in order to center on the patients and allow competition to lower list prices, **formularies should be constructed on efficacy, safety, and lowest list price.** At the very least, we need a system in which:

[1] *Health Affairs*, Health Policy Brief, "Pharmacy Benefit Managers" (Sept. 14, 2017).

- **Middlemen are paid a fixed fee based on market valu**e for their services – not based on the list price of the drug vying for formulary placement.
- Patients pay **coinsurance on the net price of a drug**, reflecting all price concessions.
- Stable patients' medications remain covered at the same level regardless of formulary changes.
- Transparency of all fees and rebates to make sure the fees (which are kept by the PBM) are not greater than the rebates and that rebate pass through is assured to those who are paying the bill for the medications.

Thank you for the opportunity to provide comments. Please don't hesitate to contact me if I can provide any additional information.

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Background: PBMs 101

Rebates and fees drive formulary design.

A formulary is the list of medications covered by a patient's health insurance plan. To construct these formularies, many insurance companies contract with pharmacy benefit managers (PBMs), who then negotiate with drug companies for rebates, discounts, and other price concessions. In exchange, the drug companies receive favorable formulary placement for their medications. Placement on the first tier of a formulary leads to greater market share, since the PBM will use cost-sharing and utilization management tools such as prior authorization, step therapy, and non-medical switching to drive patients towards that first-tier medication as much as possible.

This system raises out-of-pocket costs for patients.

A patient's coinsurances are often based on the list prices, before any of the discounts paid by drug companies to PBMs.[2] This leaves patients with the worst end of the bargain on both sides: not only are they subjected to aggressive utilization management, they are also denied the benefit of cost-sharing reductions for the medications subject to that utilization management.

PBMs often argue that they use the "savings" they negotiate off drug list prices to keep monthly insurance premiums low. Due to the lack of industry transparency, this is impossible to verify. However, even if it is true, then we currently have a health insurance system in which the sick subsidize the healthy: patients with serious chronic illnesses in need of expensive medications provide revenue that is used to slightly reduce premiums for all consumers (regardless of health status) covered by a health plan. This is the opposite of the concept of health insurance.

Questions?

Email CSRO with questions or for additional information on the issue, this request for comments, or other concerns regarding regulation or legislation on utilization management: info@csro.info.

[2] See, e.g., "New Analysis Shows Out-of-Pocket Spending Based on List Price" by Thomas Sullivan, *Policy & Medicine* (May 4, 2018).