



NATIONAL HEALTH COUNCIL

May 25, 2022

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

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

Dear Commissioners:

The National Health Council (NHC) appreciates the opportunity to respond to the Federal Trade Commission's invitation to provide public comment about the practices of Pharmacy Benefit Managers (PBMs) and their impact on patients, physicians, employers, independent and chain pharmacies, and other businesses across the pharmaceutical distribution system.

We appreciate the role PBMs play in the supply chain, using large purchasing power to negotiate lower costs for patients and the health care system. However, we are concerned that in many cases misaligned incentives, different regulatory frameworks for different insurance markets, and other market forces potentially warp the system and negatively impact access and affordability for patients, particularly those with chronic conditions and disabilities.

Furthermore, the opaque nature of our entire pharmaceutical pricing and delivery systems, including PBMs, make it difficult to fully assess the impact each stakeholder has on the costs that patients pay at the pharmacy counter and other burdens and barriers patients face in accessing and affording their care. **Therefore, we strongly believe that the FTC should exert greater oversight, undertake more research into the effect of PBMs on health care costs and access for patients, and provide useful information to patients and patient advocates. While beyond the scope of this particular request, we also urge FTC to address anti-competitive practices throughout the entire supply chain and will continue to work with Congress and the Department of Health and Human Services on policies to address affordability and access challenges wherever they exist.**

Created by and for patient organizations more than 100 years ago, NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, sustainable health care. Made up of more than 145 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic drug, and payer organizations.

The increasing cost of prescription drugs and amount patients pay out-of-pocket for medicines create significant challenges for the patient community. The NHC prioritizes policies that address the rising costs of health care, including, but not limited to, the costs of prescription medicines and affordability for patients. We support meaningful policies that promote competition to drive availability of lower-cost, high-quality products, and services. We strongly oppose policies that achieve savings at the expense of patient safety, access, affordability, or quality of care.

Among our highest affordability priorities is greater transparency in the entire drug supply chain, including manufacturers, distributors, insurers, PBMs, health care providers, and pharmacies.¹ As the NHC remains committed to ensuring adequate access to affordable, high-value medications for patients, we are supportive of the Administration's efforts to examine the role that each stakeholder has on affordability and access for patients.

Addressing Out-of-Pocket Costs

As previously stated, the current drug supply chain is driven by incentives that do not always benefit patients. Given the lack of transparency around contracting, it is often difficult for patient advocates to fully understand how incentives are driving decision-making. For example, we would welcome greater transparency about the impact that manufacturer rebates may have on patients' out-of-pocket costs. Products with an associated coinsurance often require patients to pay a percentage of the list price, not the net price. The rebates help save employers or insurers money, which may be passed to all of their beneficiaries through lower premiums. However, for many patients who are in most need of expensive medications, sharing the savings, or tying cost-sharing to the negotiated price, would more greatly benefit them. The spread between list and net prices may also create a system where incentives exist for the PBMs and insurers to favor drugs with a higher list price but larger discounts. And because the list price is higher, patient out-of-pocket costs end up being higher.

One example where this may be occurring is PCSK9 inhibitors to treat familial hypercholesterolemia (FH). Once there was competition in class, manufacturers offered them at a lower list price. However, the PBMs all chose to contract for a higher list price with higher rebates, which resulted in higher co-pays for patients.²

One particular concern for patients is the potential impact misaligned incentives may have on coverage and reimbursement for biosimilars. Biosimilars hold great promise to lower costs compared to branded biologics while maintaining an equal level of benefit. We are at a watershed moment that will determine whether biosimilars fulfill that promise. However, the manufacturing costs and price differences between branded

¹ National Health Council. Policy Recommendations for Reducing Health Care Costs.

<https://nationalhealthcouncil.org/additional-resources/policy-recommendations-for-reducing-health-care-costs/>

² The Family Heart Foundation. Why are FH patients paying a higher price for PCSK9 inhibitor treatment when a lower price is available, and what can we do about it? <https://thefhfoundation.org/fh-paying-higher-price-pcsk9i>

biologics and biosimilars is much smaller than the difference between branded small molecule drugs and their generic competitors. This could mean that PBMs have less incentive to prefer biosimilars over biologics, even when they may be as clinically beneficial and cheaper for patients. We are concerned there may be instances where misaligned incentives could encourage preference for branded biologics if manufacturers, in certain instances, offer rebates equal to, or greater than, the difference between the brand and biosimilar. The net result may be that patients pay higher cost-sharing, and development of biosimilars is discouraged.³ We encourage FTC to examine the role rebates may play on coverage of biosimilars.

The FTC should examine the impact of manufacturer rebates on people with chronic diseases and disabilities. While they may benefit from lower premiums, it is our understanding that these savings are much smaller than the higher costs they pay as a result of out-of-pocket costs being tied to list prices instead of negotiated rates. Further, we recommend FTC examine whether there are any anti-trust barriers to rethinking the way PBMs and manufacturers negotiate costs beyond rebates in ways that would reduce beneficiaries' out-of-pocket costs.

Formulary Design

Another way PBMs affect access and affordability for patients is through formulary design and requirements for utilization management such as step therapy or prior authorization. While we understand the potential benefit of utilization management in some cases, the chronic disease and disability community has become greatly frustrated by the additional burden placed on patients, families, and health care providers. For instance, studies have shown that formulary restrictions of anti-seizure medications were associated with significant delays in treatment⁴. For many disease states, delay in access to the most-needed medicine can result in serious and sometimes permanent worsening of health.

While utilization management protocols may be grounded in sound clinical decision-making, such as prior authorization to limit drug-to-drug interactions or prevent overprescribing of potentially addictive medication, the development of such protocols is typically done without much or any patient input, and the rationale for such decisions is not typically made public. We support oversight and transparency of such practices to inform the patient community as to how decisions are made that have such a direct effect on patients.

Another instance where lack of transparency is having a negative impact is that it is impossible for patients to determine if a plan has a copay accumulator when shopping for plans. This is a piece of information that can have considerable implications on a

³ Gottlieb, Scott. Capturing the Benefits of Competition for Patients. 2018.

⁴ Mehta, D., Davis, M., Epstein, A.J. et al. (2020). Impact of formulary restrictions on antiepileptic drug dispensation outcomes. *Neurol Ther* 9, 505–519. <https://doi.org/10.1007/s40120-020-00195-3>

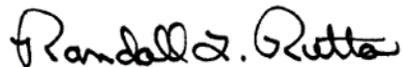
patients' out-of-pocket costs. The FTC should examine the prevalence and impact of copay accumulators and the lack of information available to patients.

Conclusion

We call for system-wide transparency and greater oversight of PBMs and the rest of the pharmaceutical supply chain. As the FTC identifies anti-competitive practices that result in less access and higher costs for patients, the NHC is ready and able to help identify or respond to policies to rectify these issues. As an example, we support the concept of patients sharing in the savings realized by rebates, whether it be through rebate passthrough or policies that tie cost sharing to negotiated rates. We also recognize the factors impacting access and affordability are numerous and immense. We therefore support oversight and transparency of not only PBMs but every part of the drug supply chain.

Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs if you or your staff would like to discuss these issues in greater detail. He is reachable via e-mail at egascho@nhcouncil.org.

Sincerely,

A handwritten signature in black ink that reads "Randall L. Rutta". The signature is written in a cursive, slightly slanted style.

Randall L. Rutta
Chief Executive Officer