

May 4, 2022

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

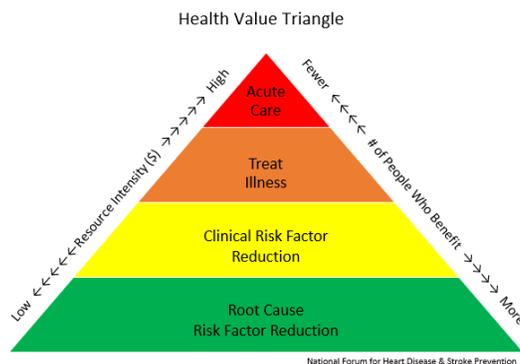
Dear Federal Trade Commissioners and Staff,

The Value & Access Collaboration, convened by the National Forum for Heart Disease & Stroke Prevention, is pleased to respond to the FTC’s Request for Information about how large, vertically integrated pharmacy benefits managers’ (PBMs’) business practices affect consumers’ access to healthcare.

The Value & Access Collaboration represents patients, clinical providers, community health workers, public health, payers, purchasers & pharma/biotech, who share the goal to “Enhance health and well-being by supporting people’s access to evidence-based care that is appropriate for them.” The Value & Access Collaboration stands for:

- Optimizing cardiovascular health and well-being for people throughout society
- Preventing cardiovascular disease (CVD) risk factors for people throughout society
- Ensuring people have access to therapies for CV risk factor reduction, and people with CVD can get the evidence-based therapies they need, regardless of socioeconomic status, geography, or genetics, and
- True transparency in costs of healthcare services and products

Patient access is fundamental to quality, equitable healthcare. The Health Value Triangle below demonstrates that focusing on the base of the health value triangle maximizes economic value and benefit.



The Value & Access Collaboration provides the following input for consideration:

- The FTC's agency is clear: 80% of U.S. consumers' access to medications is regulated by the big 3 PBMs, who themselves are largely unregulated entities.

- Some PBMs' business practices reduce people's access to therapies they need.
 - o PBMs' business practices can interfere with clinician-patient decisions about the right treatment and the provision of such treatments to the right patients at the right time, including:
 - Non-medical switching.
 - High consumer out-of-pocket costs.
 - Prior Authorization (PA) requirements and practices can be onerous and confusing for consumers and clinicians. There is a lack of transparency in some PBMs' PA requirements and reasons for denial. When a PBM would cover a similar drug on the formulary (while denying a drug not on formulary) the denial letter should state the alternative that would be approved. Instead, some PBMs leave this to clinicians and patients to figure out for themselves.
 - PA requirements that are not aligned with current clinical guidelines. Establishment of PA criteria should include experts in the disease areas treated by the drugs under consideration. There should be a clear channel of communication for professional societies and patient organizations to request a review and recommend changes.
 - Patient steering to PBM-owned pharmacies due to network limitations established by PBMs.
 - Restricting drug formularies can limit patients' medication access.
 - Limiting the number of drugs at pharmacies (bulk purchases).
 - Forcing patients to use higher price brand drugs that generate higher rebates for the PBM and higher PBM fees charged to the pharmacy.

 - o Certain PBM practices, such as setting unpredictable reimbursement rates and imposing retroactive Direct and Indirect Remuneration (DIR) fees, have forced community pharmacies out of business. The data show that pharmacy price concessions, net of all pharmacy incentive payments, escalated more than 107,400 percent between 2010 and 2020.¹
 - Due to the lack of transparency by PBMs, pharmacies are often reimbursed less than it costs to acquire the drug, and below the cost the drug is dispensed to the patient, making community pharmacy business models difficult to sustain.
 - This reduces access to needed medications and undermines health equity for people in places with limited numbers of pharmacies, such as rural areas, thus raising their risk of deteriorating health; heart attacks, strokes, and kidney

¹ <https://www.regulations.gov/document/CMS-2022-0012-0001>

failure; and need for more costly treatments.

- PBMs' sources of revenues and expenses should be transparent.
 - o Currently there is no transparency, notwithstanding assertions to the contrary by the PBM industry.
 - o The flow of rebate dollars should be transparent. Today, transparency is precluded by contracts that prohibit disclosure.
 - o Even as rebates paid to PBMs by manufacturers increase, ostensibly reducing net prices of medications, consumers' costs can (and do) increase.

- In a fully transparent model when a PBM functions as a fiduciary the drive is to achieve lowest net cost for the overall pharmacy spend – not to maximize the multiple sources or revenue of which rebates may be the largest.

We urge the FTC to illuminate how various types of PBMs work, what the rebates and DIR fees are, how they're being allocated, and where the money goes. We encourage the FTC to ask PBMs to demonstrate how money is being saved, and where the money is going as part of the pricing. Policymakers may also consider setting limits on the profit margins received by PBMs as exists for health plans.

Respectfully,

Members of the Value & Access Collaboration representing the following organizations:

National Forum for Heart Disease & Stroke Prevention (convener)

American Association of Heart Failure Nurses

American College of Cardiology

American Pharmacists Association Foundation

American Society for Preventive Cardiology

Association of Black Cardiologists

Association of State and Territorial Health Officials

BallengeRx Consulting

Family Heart Foundation

Global Healthy Living Foundation

Independent Health

Institute for Patient Access

Mended Hearts

National Alliance of Healthcare Purchaser Coalitions

National Association of Community Health Workers

National Lipid Association

Partnership to Advance Cardiovascular Health

Partnership to Improve Patient Care

Preventive Cardiovascular Nurses Association

University of Michigan Center for Value-Based Insurance Design

WomenHeart