

May 23, 2025

[Comments also submitted electronically to AnticompetitiveRegulations@usdoj.gov]

The Anticompetitive Regulations Task Force Antitrust Division U.S. Department of Justice 950 Pennsylvania Avenue NW Washington DC 20530

RE: FTC/DOJ Request for Public Comment Regarding Reducing Anti-Competitive Regulatory Barriers

The American Pharmacists Association writes in support of the Anticompetitive Regulations Task Force's request for information about "laws and regulations that make it more difficult for businesses to compete effectively, especially in markets that have the greatest impact on American households." APhA is responding to the "Healthcare" section and the impact of the vertically integrated pharmacy benefit manager (PBM) marketplace on our nation's pharmacists and their patients.

The Task Force's RFI states, "the Division will seek information from the public about laws and regulations that make it more difficult for businesses to compete effectively, especially in markets that have the greatest impact on American households," including:

"Healthcare: Laws and regulations in healthcare markets too often discourage doctors and hospitals from providing low-cost, high-quality healthcare and instead encourage overbilling and consolidation. These kinds of unnecessary anticompetitive regulations put affordable healthcare out of reach for millions of American families."

As <u>emphasized</u> by APhA President Randy McDonough PharmD, MS, BCGP, BCPS, FAPhA at a recent May 2025 Senate Judiciary Committee <u>hearing</u>, "PBM Power Play: Examining Competition Issues in the Prescription Drug Supply Chain," consolidation and the lack of competition and transparency in the PBM marketplace is endangering patient health and access to their medications, <u>closing community pharmacies</u>, that may be the only health care provider in many rural and underserved areas, and creating "a system in which profits are emphasized over patients."

APhA also supports the <u>efforts</u> of Federal Trade Commission (FTC) Chairman Andrew Ferguson's ongoing proceeding regarding the large PBMs. Ample and growing data analysis from <u>Congress</u> and the <u>states</u> clearly shows increasing evidence that consolidation of PBMs with pharmacies and <u>vertical integration in the health care space</u>, that now also includes manufacturers, is causing harm. This harm includes increases in purchasers' and patients' drug prices through price discrimination, utilization of harmful PBM fees, and other "clawback" mechanisms on pharmacies, "spread pricing," and "patient steering," for brand, generic and specialty drugs and to PBM-affiliated pharmacies.

APhA has previously <u>recommended</u> DOJ and FTC utilize several existing tools under the Administrative Procedure Act (ACA) and the Federal Trade Commission Act (FTC Act),15 U.S.C. § 45, to initiate rulemaking and bring enforcement actions to prohibit and separate health care vertical mergers that



engage in unfair methods of competition, or unfair or deceptive acts or practices in or affecting commerce, or actions that have affected acquisitions not in the public interest.

APhA has also urged the FTC to address the issue of health care insurance brokers and the kickbacks they receive from PBMs for securing business. The legality and appropriateness of these financial arrangements have not been fully investigated or illuminated. They add significantly to the cost of health care and may be used as a tactic to further restrict trade in the employer-purchased insurance market, including PBM selection by not presenting employers with the broadest range of options for benefit management, such as with smaller, transparent PBMs.

President Trump also recently issued <u>Executive Order 14273</u>, "Lowering Drug Prices by Once Again Putting Americans First," and APhA has provided <u>recommendations</u> to implement "Sec. 8 Reevaluating the Role of Middlemen" for PBM reforms based on leading actions taken in the states.

The Task Force also cites that "President Trump issued <u>Executive Order 14192</u> declaring 'the policy of the executive branch "to be that federal agencies should 'alleviate unnecessary regulatory burdens placed on the American people." "Consistent with this policy, on Feb. 19, President Trump signed <u>Executive Order 14219</u> directing agencies to "initiate a process to review all regulations" and identify regulations that, among other things, "impose undue burdens on small businesses and impede private enterprise and entrepreneurship." The consolidation of the PBMs matches this description.

An increasingly consolidated vertically merged health care marketplace has led to the big three vertically merged PBM companies of today, which negates adding new market entrants that will allow the same level of competition in the health care space. It also discourages new market entrants as the big three vertically merged PBMs control such a high market share. For example, such consolidation acts as a deterrent to smaller PBMs and community pharmacies' use of Pharmacy Services Administrative Organizations (PSAOs) to contract on their behalf. These PSAOs are no match for the PBMs. In 2013, the Government Accountability Office (GAO) conducted a <u>study</u> on the role and ownership of PSAOs and stated that "over half of the PSAOs we spoke with reported having little success in modifying certain contract terms as a result of negotiations. This may be due to PBMs' use of standard contract terms and the dominant market share of the largest PBMs. Many PBM contracts contain standard terms and conditions that are **largely non-negotiable** [emphasis added]."

The Task Force also cites "Regulatory capture," "a well-studied phenomenon in which agencies become "captured" by special interests and big businesses, rather than serving the interests of the American people." The FTC has recently issued two interim staff reports, with the most <u>recent</u> finding that the "PBMs charge significant markups for cancer, HIV, and other critical specialty generic drugs," However, while the FTC is the nation's premier antitrust enforcer, as <u>documented</u> by a former FTC official, FTC's track record, or lack thereof, is concerning when it comes to PBMs.

There are a number of actions the FTC and DOJ, working with Congress, could take to rein in the PBMs, including:

• Requiring "PBMs to act as fiduciaries to their clients, including health plans, employers, and public programs. This would legally obligate them to make decisions that are in the best interest



- of plan sponsors and program participants, addressing the fundamental misalignment of incentives that exist today, with penalties for noncompliance."
- Enforcing the 1936 Robinson-Patman Act, which "bans payments to a buyer/reseller for marketing and other services in connection with the resale, "unless such payment or consideration is available on proportionally equal terms to all other customers competing in the distribution of such products or commodities."
- Applying the Anti-Kickback Statute (AKS) to Pharmaceutical Rebates and Excluding Rebates from the AKS Safe Harbor: HHS' Office of Inspector General (OIG) has confirmed that payments to PBMs under rebate agreements are not covered by an AKS safe harbor for discounts "if they are not passed through to any buyer." In 2020, the first Trump Administration's OIG finalized its previously abandoned 2019 proposal to exclude certain rebates paid by drug manufacturers from the discount safe harbor to the federal anti-kickback statute (AKS). The final rule was intended to implement President Trump's blueprint for lowering prescription drug prices and patient out-of-pocket costs, as well as President Trump's Executive Order 13939, "Lowering Prices for Patients by Eliminating Kickbacks to Middleman," but was delayed by the Biden Administration and the Inflation Reduction Act until 2027.

If you have any questions regarding these comments and would like to meet with APhA to discuss restoring competition to the PBM and health care marketplace to protect our nation's community pharmacies, patients, and rural and underserved communities, please contact APhA at mbaxter@aphanet.org.

Sincerely,

Michael Baxter

Michael Baxter Vice President, Government Affairs

cc: Assistant Attorney General Abigail Slater