

**Solicitation for Public Comment to Understand Lack of Competition and Contracting Practices that
May be Contributing to Drug Shortages**

I. Background

Multiple agencies within the U.S. government would like to collect additional information about the root causes of and potential solutions to drug shortages. All players within the drug supply chain are intrinsically linked and thus the actions of any market participant can determine whether a drug experiences supply disruptions or shortages. Accordingly, the Federal Trade Commission (FTC), after consulting with the U.S. Department of Health and Human Services (HHS), invites public comment regarding lack of competition and contracting practices by large healthcare group purchasing organizations (GPOs)¹ and drug wholesalers.² We are seeking input regarding these entities' impact on generic pharmaceutical and related markets. This information may inform a better understanding of the root causes of and potential solutions to drug shortages.

II. Solicitation of Public Comments

Accordingly, the FTC and HHS are seeking comments, documents, and data regarding the following topics:

- Whether and to what extent manufacturers, GPOs, and drug wholesalers are complying with their legal obligations under Section 3 of the Clayton Act (15 U.S.C. § 14) and the Robinson-Patman Act (15 U.S.C. § 13 et seq.);
- Whether and to what extent the available protections for GPOs under the Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)(3)(C) and 42 C.F.R. § 1001.952(j)) affect lack of competition, contracting practices by GPOs, and drug shortages;
- Whether and to what extent lack of competition among GPOs and drug wholesalers impacts patients, hospitals, healthcare providers, pharmacies, generic manufacturers, and other suppliers;
- Whether and to what extent lack of competition among GPOs and drug wholesalers impacts smaller healthcare providers and rural hospitals;
- Whether and to what extent lack of competition among GPOs and drug wholesalers disincentivizes suppliers from competing in generic drug markets;
- The impact of GPO and drug wholesalers' contracting practices, including re-bidding provisions, most-favored nation pricing and similar clauses, as well as any other relevant

¹ As used herein, "GPOs" refer to entities that broker deals for generic pharmaceuticals and other medical supplies between healthcare providers—including hospitals, physicians, nursing homes, and home health agencies—and manufacturers, distributors, and other vendors who sell to healthcare providers.

² As used herein, "drug wholesalers" refer to entities that distribute brand, generic, specialty, and over-the-counter pharmaceutical products to retailers (including chain, independent, and large retailers) as well as hospitals and other healthcare providers.

contract terms or pricing or compensation models on generic manufacturers and other suppliers;

- The impact of GPO compensation models, which may rely on rebates, chargebacks, and administrative fees from manufacturers in exchange for favorable treatment, on generic manufacturers and other suppliers;
- GPO and drug wholesalers' practices with respect to generic manufacturers and other suppliers, including the usual process of negotiations, the use of exclusive or near-exclusive contracts, the use and terms of failure-to-supply clauses (duration, compensation, and exclusion criteria), parties' criteria for selecting suppliers, and all parties' sources of compensation;
- GPO contracting practices with respect to hospitals and other healthcare providers, including the normal process for negotiations, the use of market-share or volume-based rebates, the use of manufacturer-quality information, the use of and terms of failure-to-supply clauses, and the terms, source, and disclosure of GPO compensation;
- Drug wholesalers' contracting practices with respect to pharmacies, hospitals, and other healthcare providers, including the normal process for negotiations, the use of market-share or volume-based rebates, the use of manufacturer-quality information, and the terms, source, and disclosure of drug wholesalers' compensation;
- Instances of hospitals, pharmacies, or healthcare providers being contractually prohibited or disincentivized from purchasing either lower-cost or higher-quality products as the result of GPO or wholesaler contractual policies or restrictions;
- Evidence of or instances in which the market power of GPOs or drug wholesalers in upstream or downstream markets directly contributed to a reduction in the number of suppliers, less reliable supply chains, or drug shortages;
- Information regarding how GPOs and drug wholesalers' contracting practices differ based on the type of product being purchased (e.g., an injectable);
- Examples of approaches that have been used to successfully alleviate the adverse effects of actual drug shortages or to avoid potential shortages;
- Examples of policies, programs, methods, and innovations that may help keep drug costs low while also incentivizing pricing that would allow for continued investment in manufacturing-quality systems, which, in turn, can help prevent or mitigate drug shortages;

- What changes could be made in GPO contracting practices to incentivize manufacturers to maintain a steady and reliable supply of high-quality products, while also allowing these products to be purchased by healthcare providers at an affordable price;
- Any other similar issues or concerns regarding GPOs or drug wholesalers that may contribute to drug shortages as the public deems relevant.

We encourage the public to comment by submitting written comments, documents, and data addressing these topics. Comments will be posted on regulations.gov website. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential or sensitive information that you or a third party may not wish to be posted.