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April 9, 2024

Hon. Lina M. Khan
Chair
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Hon. Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Dear Chair Khan and Secretary Becerra,

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the request for information entitled "***Solicitation for Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages***," (February 14, 2024), issued by the *Federal Trade Commission and the U.S. Department of Health and Human Services.*

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 158 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened participation in the AAMC by U.S. and international academic health centers.

We appreciate the agencies' attention to the issue of drug shortages, which directly impacts our member teaching health systems and hospitals, affecting their ability to provide care to the patients and communities they serve. Based on the American Society of Health-System Pharmacists (ASHP) and University of Utah drug shortages database, the United States reported over 300 active drug shortages in 2023.[1] These shortages dramatically impact patient care, and although drug shortages are an enduring problem, they have increased acutely in recent years. Between March 2018 and March 2023, active drug shortages rose by almost 50%.[2] Generic drugs are predominantly impacted by shortages, with 67 percent of the drugs that went into shortage between 2013 and 2017 being generic products according to the Food

[1] Fox, Erin, "Drug Shortage Statistics," American Society of Health-System Pharmacists, March 31, 2023, https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics.
[2] Ibid.

and Drug Administration (FDA) .[3] These shortages can have devastating consequences for patient care such as treatment delays or shifting care towards alternative (and sometimes, less effective) treatment regimens.[4] Additionally, drug shortages add hundreds of millions of dollars in labor costs to health systems across the United States due to additional hours of labor needed to mitigate and manage drug shortages to ensure that patients are able to access needed medications for care.[5] These additional expenses needed to manage and mitigate shortages create a substantial burden on an already impacted labor market, which heightens the impact to providers' ability to care for patients. The root causes of drug shortages have been researched and analyzed by policymakers and stakeholders alike, including evaluating vulnerabilities in the pharmaceutical supply chain and economic factors. These findings have shown that the causes are complex and multi-factorial and require more than a one-size fits all solution.

While we welcome this exploration of the causes of drug shortages, we are concerned that the narrow focus of this RFI on group purchasing organizations (GPOs) and drug wholesalers does not consider the full picture behind what causes generic drugs to be susceptible to shortage. As indicated by the RFI, GPOs are often utilized by providers in assisting with the sourcing of drugs as well as an array of items and supplies used by providers. Traditional healthcare GPOs serve as a critical link between healthcare providers and manufacturers by assisting in increasing the efficiency of contracting for high-quality medical products and services, including prescription drugs. This in turn allows health systems and providers to ensure a stable, resilient supply of drugs and materials needed to provide safe, effective treatment to patients. However, it is important to note that GPOs themselves do not purchase or buy the products. Rather GPOs assist in negotiating contracts with manufacturers that health systems, hospitals and other providers can then use when making their own purchases. Many AAMC member health systems and teaching hospitals utilize GPOs to alleviate burden and additional non-clinical workforce needs associated with purchasing. This allows health systems to further stretch scarce resources to meet patient needs. The utilization of GPOs also allows for providers to have confidence in consistent and reliable access to essential drugs, medical supplies, and other products necessary for patient care, further enhancing efficiency and quality in the healthcare services our members provide.

GPOs serve a significant role in health systems' ability to purchase drugs and other needed items by aggregating health systems' purchasing power to negotiate competitive contracts with manufacturers. Because of this, GPOs provide a critical link between providers, manufacturers, and government officials in addressing and preventing drug shortages. GPOs have the unique ability to provide additional data tracking that allows them to work with providers and manufacturers to identify alternative sourcing or products when shortages arise. The additional data tracking that GPOs offer creates an array of data including information on demand surges and hot spots, which allows for manufacturers to receive additional notice of demands in order to quickly increase supply and ensure providers retain a reliable supply of critical medications and supplies for their patients. GPOs maintain established relationships with providers and manufacturers well before increased demands or shortages arise, giving them the

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[3] United States Senate Committee on Homeland Security and Governmental Affairs, HSGAC Majority Report: Short Supply: The Health and National Security Risks of Drug Shortages, (Washington, D.C.: HSGAC, 2023), https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf

[4] Fox, Erin, "Drug Shortage Statistics," American Society of Health-System Pharmacists, March 31, 2023, https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics.

[5] https://newsroom.vizientinc.com/en-US/releases/new-vizient-survey-finds-drug-shortages-cost-hospitals-just-under-360m-annually-in-labor-expenses#:~:text=New%20Vizient%20Survey%20Finds%20Drug,M%20Annually%20in%20Labor%20Expenses

unique ability to swiftly react and assist with providers' and patients' needs. We saw this process in action during the COVID-19 public health emergency as GPOs assisted health systems in securing critical supplies. GPOs also utilize certain principles to limit the impact of drug shortages when they occur, including implementing drug mitigation strategies in order to minimize the impact of a shortage and allow the market to recover quicker.

The purchasing contracts utilized by GPOs allow manufacturers to have greater confidence in their financial stability and enables them to continue producing supplies as these contracts provide predictability in the volume of sales for their products. These contracts also serve as advance notice of production needs to avoid shortages; however, in the event of a shortage, GPOs are able to quickly identify additional manufacturers and create incentives by guaranteeing purchase volumes and potential profits for new suppliers. GPOs also evaluate manufacturer reliability, including the stability of their supply during the sourcing process in order to reduce administrative burden related to identifying additional manufacturers to meet demand during a supply chain disruption.

Through these contract negotiations, health systems and other providers can realize cost savings and create cost efficiencies that benefit the whole healthcare ecosystem, including the patients they serve. Based on a 2018 survey and report on GPO savings, it was estimated that over a five-year (2017 to 2021) and ten-year (2017 to 2026) period, the negotiated rates amounted to $197.9 billion and $456.6 billion in GPO cost savings respectively. The report also estimates savings to Medicare and Medicaid of $116.3 and $90.2 billion respectively for the 10-year period of 2017-2026 when GPOs are used to negotiate hospital and nursing home expenditures.[6] These savings are crucial to healthcare facilities, as many lack the infrastructure and purchasing power needed to negotiate for essential supplies on their own. This enables providers and health systems to further stretch scare resources and ensure a steady, reliable supply of drugs and supplies are available to provide needed patient care. In addition to cost savings, GPOs consider several additional factors when negotiating contracts for providers to purchase drugs, including manufacturing quality and the ability of the manufacturer to meet supply demands. This often means that a bid for a contract may not be selected due to price alone and that a manufacturer's inability to meet quality and resilience needs can also hinder sales.

To identify the root of the issues related to drug shortages and maintain cost savings for patients and providers, we urge the agencies to explore policy options that focus on these quality and resiliency needs. Some of these policy options include bolstering efforts around further developing a quality rating system for manufacturers, developing payment adjustments for generic essential medications frequently in shortage, and increasing supply chain transparency. As it pertains to quality, we urge the agencies to work with the FDA to further develop and incentivize manufacturers to participate in the Quality Management Maturity (QMM) rating system as well as the Quality Metrics (QM) Reporting Program so that these programs are predictive of supply chain and manufacturing vulnerabilities. This will allow insight into potential quality issues for specific drugs before they occur, which can then inform policymakers, manufacturers, GPOs, providers, and other stakeholders' decisions around mitigation measures. We also encourage the agencies to work with Congress and the Centers for Medicare and Medicaid (CMS) to consider payment adjustments to providers for generic essential medications frequently in shortage, when contracting with manufacturers that agree to supply chain mitigation and resiliency requirements, such as

[6] Dobson DaVanzo & Associates, LLC, "A 2018 UPDATE OF COST SAVINGS AND A MARKETPLACE ANALYSIS OF THE HEALTH CARE GROUP PURCHASING INDUSTRY" (2019), https://supplychainassociation.org/wp-content/uploads/2019/05/HSCA-Group-Purchasing-Organizations-Report-FINAL.pdf

participation in the QMM rating system to further incentivize manufacturers to participate. Providing payment adjustments to providers that contract with manufacturers participating supply chain mitigation and resiliency requirements would incentivize providers to select contracts with manufacturers that are more reliable and are more likely to produce a quality supply of products. In turn this will ensure providers contract with reliable, quality manufacturers and reduce the risk of shortages arising from issues related to manufacturing quality, delays, or discontinuations. Ultimately, this will protect patients' safety and access to needed care.

In addition to this, improving supply chain transparency would enhance the ability to predict and respond to potential shortages or disruptions. Improvements to transparency that would impact the ability to respond to potential shortages include notification from manufacturers of permanent discontinuances and significant interruptions in manufacturing, expanding shortage related information shared with the FDA to include demand spikes and other fluctuations, and enhancing the functionality of the FDA's Drug Shortage List to include more information on the severity and causes of a shortage as well as a manufacturers' plans to mitigate the shortage. Lastly, the FDA utilizes insights and information provided by GPOs on supply chain disruptions. GPOs assist the FDA by providing information on fill rates, market fluctuations, demand spikes, and supply disruptions. The increased transparency into this information allows all stakeholders to better prepare and plan for potential shortages prior to the shortage impacting patient care.

**CONCLUSION**

Thank you for the opportunity to comment on this request for information. We would be happy to work with the FTC and HHS on any of the issues discussed or other topics that involve the academic community. If you have questions regarding our comments, please feel free to contact Katie Gaynor at kgaynor@aamc.org.

Sincerely,

Jonathan Jaffery, M.D., M.S., M.M.M., F.A.C.P.

Chief Health Care Officer

cc: David Skorton, M.D., AAMC President and Chief Executive Officer