Charles N. Kahn III
President and CEO

May 30, 2024

The Honorable Lina Khan
Chair
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Solicitation for Public Comment; Docket No. FTC-2024-0018 (Feb. 14, 2024)

Dear Honorable Chair Khan and Honorable Secretary Becerra:

The Federation of American Hospitals (FAH) appreciates this opportunity to submit comments to the Federal Trade Commission (FTC) and the Department of Health and Human Services (HHS) (collectively, the Agencies) regarding the *Solicitation for Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages,* Docket No. FTC-2024-0018, released February 14, 2024 (the Solicitation).

The FAH is the national representative of more than 1,000 tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in urban and rural areas across 46 States, Washington DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services to patients in diverse communities across the country. We offer these comments to provide our perspectives on the critical role that group purchasing organizations (GPOs) play every day to promote a steady, affordable supply of vital drugs and other supplies for our healthcare delivery system and the patients, caregivers, and communities they serve. We note that since FAH members primarily engage with GPOs for the purchase of pharmaceutical drugs, our comments will focus on GPOs which typically do not function as drug wholesalers.

General Comments

Modern-day drug shortages are fundamentally a problem of supply, not demand. Demand for drugs does sometimes fluctuate in unpredictable ways – for instance, during a global pandemic – but these circumstances are decidedly the exception, not the rule. Instead, the great majority of shortages involve ***supply-side*** dynamics when a manufacture is unable to deliver enough products to satisfy predictable, recurring demand.[1] Thus, we respectfully urge the Agencies to focus their policy interventions on addressing these supply-side market dynamics, rather than on unspecified "lack of competition and contracting practices" by demand-side purchasers, such as GPOs, which maintain efficiency, consistency, and significantly lower costs in an otherwise uncertain market.

GPOs Provide Multiple Services to Promote a Steady, Affordable Supply of Vital Drugs for Patients and the Healthcare Delivery System

GPOs are an important part of the United States healthcare infrastructure and play a critical role in promoting a steady, affordable supply of vital drugs for patients and the entire supply chain. GPOs innovate through multiple roles and services offered to hospital providers that are focused on creating system wide efficiencies and significantly lowering costs while establishing consistency and certainty across our healthcare delivery system – all of which increase access for patients. While manufacturers may have a more narrow and myopic focus on individual products, a GPO's vision spans the broad spectrum of pharmaceuticals and supplies that hospitals and their patients need.

GPOs are structured to engage in initiatives to ensure resiliency in the pharmaceutical supply chain, with a focus on anticipating and mitigating drug shortages to ensure patient access to essential medications. For instance, one GPO program helps protect against drug supply interruptions by mapping the optimal supply chain for mission-critical products, including manufacturing and active pharmaceutical ingredient (API) redundancies, geographic diversification, and quality profiling of manufacturers supplying critical inputs along the supply chain. Another GPO program involves working with suppliers to ensure availability of on-shore buffer inventory of essential medications critical to clinicians' ability to provide immediate patient care.

[1] *See, e.g.*, Berkeley Lovelace Jr., *How One U.S. Drugmaker Contributed to the Escalating Drug Shortage Crisis*, NBC NEWS, July 16, 2023 ("In December, Intas Pharmaceuticals, a generic drug manufacturer based in India, suspended production after an FDA inspection last year cited numerous quality concerns. The suspension caused a widespread shortage of cisplatin, a chemotherapy drug used for a variety of cancers, including testicular, bladder, cervical and ovarian. Global Pharma, also based in India, recalled its EzriCare Artificial Tears eye drops this year after the products were linked to highly drug-resistant bacterial infections that resulted in four deaths. An FDA inspection found that the company did not follow proper protocol to prevent contamination of its products."); Jen Christensen, *New Drug Shortages in the US Increased Nearly 30% in 2022, Senate Report Finds,* CNN, Mar. 22, 2023 ("Only one company made certain albuterol products used for continuous nebulizer treatment. The manufacturer that shut down, Akorn Operating Co., filed for Chapter 11 bankruptcy in May 2020."); Christopher Rowland, *The Albuterol Shortage is About to Get Worse*, WASH. POST, Mar. 1, 2023 ("Children's hospitals across the country lost a supplier of a common respiratory medicine with the sudden shutdown of an Illinois manufacturing plant last week, which specialists warned will prolong shortages of an important treatment for kids with RSV and asthma who show up in emergency rooms."); April Dembosky, *Saline Shortages Create Troubles for U.S. Hospitals*, PBS NEWS HOUR, June 25, 2014 ("The procurement director for a group of dialysis centers says his [saline] provider, Baxter, told him the main problem was winter weather. Snow and ice storms in the Midwest were delaying trucks headed for California.").

Indeed, their relationships with, and line of sight into, drug suppliers and their supply chains enables GPOs to anticipate and quickly communicate regarding imminent drug shortage matters in service to hospitals and other providers. For example, when a major pharmaceutical company's manufacturing facility was hit by a tornado in 2023, GPOs were able to obtain and communicate information to providers and distributors about the true scope of the impact to ensure proactive allocations and alleviate panic buying that might have worsened a shortage.

GPOs conduct continual evaluations of the marketplace to ensure manufacturers with which they contract deploy best practices and have the ability to robustly engage in production and can meet GPO member needs. Individual hospitals, on their own, are not designed to engage in these processes, as it would be very inefficient – diverting limited resources and detracting from their primary mission, which is to deliver needed medical care to patients.

GPO services also include data analysis and benchmarking, innovative technology integration, market research, emergency preparedness, natural disaster response, and reducing medical errors by helping to standardize some of the product use in hospitals and educating clinicians on best practices. They also host member educational forums to share best practices and conduct data review of world, national, regional, and local events to help anticipate supply chain disruptions, while examining spending data to ensure efficiency, value, and quality in purchase pattens for pharmaceutical drugs.

GPOs Support the Economic Health of Hospitals

We caution the Agencies on the risks of overdeterrence in the GPO industry, as this could undermine the multitude of services GPOs provide that benefit patients and our health delivery system. Supply cost management is critical to keeping hospitals financially solvent as they grapple with escalating labor costs, among other inflationary pressures that exceed revenue growth, and if supply chain expenses are not contained hospital finances would erode even further, and for some, to potentially unsustainable levels.

FAH member hospitals choose to engage the services of GPOs because, due to their sophisticated business model, they are in the best position to navigate a complicated, critical marketplace in a manner that best serves the interests of patients and their hospital providers. The efficiencies and cost savings offered by GPOs are crucial to keeping a hospital open and preserving a full range of service lines. For as vital as hospitals are to patients and communities, hospitals often run on incredibly thin margins. On a national basis, average hospital operating margins for CY2023 were just 2.3%.[2] These margins are often even lower for rural hospitals, small hospitals, and hospitals that primarily serve indigent populations.[3] Hospitals are especially

[2] Kaufman, Hall & Associates, LLC, *National Hospital Flash Report* (Jan. 2024), available at https://www.kaufmanhall.com/sites/default/files/2024-01/KH_NHFR-2024-01-V2.pdf.

[3] *See generally* American Hospital Association, RURAL HOSPITAL CLOSURES THREATEN ACCESS: SOLUTIONS TO PRESERVE CARE IN LOCAL COMMUNITIES (2022) ("Many rural hospitals were in precarious financial positions even before the COVID-19 pandemic, and the pandemic has exacerbated the challenges that many rural hospitals were already experiencing, including workforce shortages, limited access to critical supplies and aging infrastructure."); Lukas K. Gaffney & Kenneth A. Michelson, *Analysis of Hospital Operating Margins and Provision of Safety Net Services*, JAMA Network Open Vol. 6,4 (Apr. 18, 2023) ("Urban location was associated with a higher operating margin compared to rural areas (2.1 percentage points; 95% CI, 0.9 to 3.4 percentage

vulnerable to spikes in inflation, because while hospitals' costs (*e.g.*, wages, drugs, and supplies) tend to rise over periods of weeks or months, their revenues (payments from private and government payors) tend to rise only over periods of years, and often understate the inflationary impact. For example, the below table[4] shows how the Centers for Medicare and Medicaid Services' (CMS') forecast of the market basket for Medicare payment updates for inpatient hospital services compares to the actual market basket based on later data since FY 2020:

IPPS Market Basket	FY 2021	FY 2022	FY 2023
Forecast Used in the Update	2.4	2.7	4.1
Actual Based on Later Utilization	3.0	5.7	4.6
Difference	-0.6	-3.0	-0.5

Low margins and vulnerability to inflation leave little room for error in how hospitals procure drugs and supplies. A relatively small-seeming increase in drug costs can have a material impact on ongoing hospital operations, reducing the capacity to make investments in care and the talent necessary to serve its community now and into the future. We therefore urge serious caution before the Agencies pursue policy interventions that could have the effect of increasing hospitals' costs, with negative consequences for patients.

GPOs Have Long Been Recognized as Pro-Competitive

GPOs have long been recognized as engines that infuse procompetitive benefits into the marketplace. From 1996 until just last year, the enforcement policy of the FTC and Antitrust Division (together, the Antitrust Agencies) was that "Most joint purchasing arrangements among hospital or other healthcare providers do not raise antitrust concerns."[5] Until last year, in fact, the Antitrust Agencies recognized an outright "safety zone" for "joint purchasing arrangements" that meet two conditions, which the overwhelming majority of GPOs do.[6] We note, however, that in 2023, this longstanding safety zone – along with the rest of the *Statements of Antitrust Enforcement Policy in Health Care* – were withdrawn with little explanation[7] focused around

points)… [U]ncompensated care, undercompensated care, and area disadvantage were each associated with a lower operating margin.").

[4] OACT, 4th quarter 2022 release of the market basket information with historical data through the 3rd quarter of 2022 (https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/marketbasketdata) for the actual update based on later utilization. Data for FY 2023 remains an estimate as it only reflects data through the 3rd quarter of FY 2022.

[5] U.S. Department of Justice & Federal Trade Commission, *Statements of Antitrust Enforcement Policy in Health Care* (Aug. 1996), Statement No. 7 (subsequently withdrawn). As this guidance explained, "Such collaborative activities typically allow the participants to achieve efficiencies that will benefit consumers." The guidance added that "The existence of a large number and variety of purchasing groups in the health care field suggests that entry barriers to forming new groups currently are not great."

[6] The safety zone conditions were (i) that the purchases under the joint purchasing arrangement account for less than 35% of the total sales of a purchased product or service in a relevant market; and (ii) that the cost of the products and services purchased jointly account for less than 20% of the total revenues from all product or services sold by each competing participant in the joint purchasing arrangement.

[7] With all due respect to the Antitrust Agencies, the withdrawal of the *Statements of Antitrust Enforcement Policy in Health Care* was done in an opaque fashion and has created needless business uncertainty for the healthcare community. The FAH urges the Antitrust Agencies to provide more transparency around the reasons for

information-sharing,[8] an issue which is not relevant to GPOs. Respectfully, the FAH believes that the withdrawal of the antitrust safety zone for joint purchasing arrangements, such as GPOs, was not just unwise, but arbitrary and unjustified and has caused undue business uncertainty for GPOs and their customers. Therefore, the FAH urges the Antitrust Agencies to restore this safety zone in its entirety.

B. Specific Comments to Solicitation

The FAH offers the following responses to certain specific items listed in the Solicitation:

Impact on Smaller Healthcare Providers and Rural hospitals

Healthcare providers in small, rural, and underserved communities particularly benefit from the cost savings and stability of supply that GPOs promote. Rural and small hospitals, and those in underserved communities, often have thin margins and the least practical ability to negotiate with drug manufacturers directly. These are therefore the hospitals – and by extension their patients and communities – that especially depend on GPOs and benefit from the multitude of services that a GPO can provide. GPOs are able to reduce transaction costs for smaller hospitals by consolidating the number of negotiations that take place, allowing them to take advantage of these efficiencies, while also being able to access more advantageous terms and pricing that would otherwise only be offered to larger health system purchasers.

Contractual Provisions for Lower-Cost or Higher Quality Products

The Solicitation inquires whether healthcare providers are "*contractually prohibited or disincentivized from purchasing either lower-cost or higher-quality products as a result of GPO or wholesaler contractual policies or restrictions.*" The experience of FAH members is just the opposite. The reason why hospitals use GPOs is to secure a cost-effective, high-quality, reliable supply of goods. In the rare circumstances where, for whatever reason, a GPO is unable to secure agreements with suppliers of cost-effective, high-quality supply of goods desired by its members, the GPO generally will not prevent or discourage its members from purchasing supplies from manufacturers directly. Thus, it is inaccurate to posit that "lack of competition" among GPOs may be contributing to drug shortages; quite to the contrary, when drugs are scarce, manufacturers have little difficulty reaching the highest bidder.

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these withdrawals and, going forward, to seek notice and public input before making sweeping policy decisions that may upset longstanding business arrangements – especially in areas that are critical to patient-facing operations.

[8] *See* Federal Trade Commission, Announcement, *Federal Trade Commission Withdraws Healthcare Enforcement Policy Statements* (July 14, 2023) ("Moreover, the Statements may be overly permissive on certain subjects, such as information sharing. In particular, companies have sometimes used the safety zone for information exchanges in contexts and industries that were never contemplated by the agencies, including to share competitively sensitive wage and benefit information with other employers."); Department of Justice, Press Release, *Justice Department Withdraws Outdated Enforcement Policy Statements* (Feb. 3, 2023) (As a result, the statements are overly permissive on certain subjects, such as information sharing, and no longer serve their intended purposes of providing encompassing guidance to the public on relevant healthcare competition issues in today's environment."); Remarks of PDAAG Doha Mekki at GCR Live (Feb. 2, 2023) ("These [*Statements*] also recognize "safety zones" around the exchange of competitively-sensitive information. As I previously discussed, the Division is concerned that the factors do not consider the realities of a transformed industry and, therefore, understate the antitrust risks of competitors sharing competitively-sensitive information.").

Approaches to Avoiding Potential Shortages

With respect to the item in the Solicitation about "*approaches that have been used … to avoid potential shortages*," we note that GPOs are increasingly incorporating analyses of supply-chain resiliency into their procurement processes. For example, as discussed above, GPOs increasingly consider "resiliency" factors like a manufacturer's historical reliability rate; whether a manufacturer may be at risk of bankruptcy; whether its production facilities are located in areas susceptible to natural disasters; and whether it has backups and redundancies built into its manufacturing footprint. Then, after the bidding process concludes, GPOs and wholesalers will monitor factors like foreign port closures and transportation bottlenecks, all in an effort to anticipate and prevent shortages before they start. These resiliency analyses serve to prevent manufacturers from bidding too low and they are precisely the sorts of things that small individual hospitals do not have the resources to do on their own.

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The FAH appreciates this opportunity to submit these comments. If you have any questions, or if there is any other way that we can assist the Agencies as they consider the Solicitation, please contact me or any member of my staff at (202) 624-1500.

Sincerely,