HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

May 30, 2024

Submitted electronically via https://www.regulations.gov/docket/FTC-2024-0018/document

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The Honorable Lina Khan
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Re: Federal Trade Commission (FTC) and Department of Health and Human Services (HHS) Joint Request for Information (RFI) on Generic Drug Shortages (Docket No. FTC-2024-0018)

Dear Chair Khan, Secretary Becerra, Commissioner Slaughter, Commissioner Bedoya, Commissioner Holyoak, and Commissioner Ferguson:

On behalf of the Healthcare Supply Chain Association (HSCA), which represents the nation's leading traditional healthcare group purchasing organizations (GPOs), we appreciate the opportunity to provide our response to the joint RFI published by the FTC and HHS on February 15, 2024.

As detailed below, on behalf of the healthcare provider members they serve, GPOs work tirelessly to prevent and mitigate shortages of drugs and other products by applying their unique sourcing expertise and deep insights into the healthcare supply chain. We hope you will find this information helpful.

Executive Summary

Traditional healthcare GPOs serve as the sourcing and contracting partners to healthcare providers across the country, as well as offer a wide range of services that enhance quality of care, improve operations, and reduce costs. GPOs play a critical role in the healthcare ecosystem, including by negotiating fair contracts with a broad spectrum of suppliers of pharmaceuticals and other medical products, bringing transactional efficiencies, and enabling providers to focus on providing the best possible care to patients. GPOs are particularly valuable for many smaller and rural hospitals – many of which are at risk of closing – by giving them access to competitive pricing and favorable terms on essential supplies on par with their larger healthcare counterparts.

GPOs help foster a fair and competitive market for procurement services, taking a comprehensive approach to sourcing and contracting that not only accounts for competitive prices offered but also non-financial criteria such as the quality, reliability, and stability of supply. The GPO model incentivizes strong supply chain mapping and supplier resiliency. GPOs often enter contracts with multiple suppliers, enabling members to choose among alternate supply lines.

The use of GPOs is entirely voluntary for both providers and suppliers. Providers often maintain multiple GPO relationships, frequently shift their GPO membership arrangements, and procure supplies directly from suppliers which, likewise, may choose to not contract with a GPO. GPOs operate in a market environment in which they face competition from numerous other entities and purchasing channels.

There are several misunderstandings about GPOs and their role in the procurement of pharmaceuticals in particular. Importantly, traditional healthcare GPOs do not: (i) place orders for products on behalf of healthcare provider members/buyers; (ii) take title to products or manage distribution of products ordered by provider members; (iii) dictate the prices charged or production volumes generated by manufacturers; (iv) impose or mandate contracts or purchase obligations on providers; (v) earn or retain rebates based on provider member purchases; or (vi) play a significant role in the volume of prices of products produced for, or fulfilled by, retail pharmacies, such as oral solid ADHD medicines or self-administered injectables such as GLP-1 inhibitors or epi-pens. Importantly, nearly half of the Food and Drug Administration (FDA)-identified shortage drugs are drugs for which (i) GPOs do not contract; (ii) there is inherently no manufacturer competition to facilitate negotiations (e.g. branded medications); and/or (iii) sales pursuant to GPO contracts represent only a small portion of the market share (e.g. retail vs. primary care setting).

In the pharmaceutical supply chain, traditional healthcare GPOs are distinct from pharmacy benefits managers (PBMs) and wholesalers – GPOs are provider-aligned, net-price driven, and do not take possession of or title to product. GPOs primarily negotiate point-of-sale price reductions, and to the extent there are any post-sale rebates earned on member purchases, those rebates are passed entirely through to the providers that earn them and reflected in their Medicare cost reports. In contrast, PBMs work primarily in the retail prescription market with health insurance and plan sponsors, and PBM-operated "GPOs" aggregate rebates owed to the PBMs themselves. Wholesalers similarly aggregate purchasing and compete in the retail pharmaceutical market, purchasing and taking possession of products themselves.

GPOs actively work to prevent and mitigate drug shortages, which are fundamentally antithetical to the GPO model. GPOs offer innovative programs to protect against supply chain interruptions and, further, support government efforts to enhance supply chain resiliency and mitigate drug shortages. HSCA and its members proudly participate in numerous government-led and public-private initiatives designed to prevent drug shortages, and GPOs are at the forefront of drug shortage policy discussions, including offering a number of recommendations to policymakers in this important area.

HSCA respectfully offers the following responses to the joint RFI:

Overview of Traditional Healthcare GPOs.[1]

Healthcare providers initially formed GPOs in the early 1900s as an efficient means to aggregate purchasing volume, drive competition among suppliers, and reduce healthcare costs. Today, traditional healthcare GPOs serve as sourcing and contracting partners to hospitals, long-term care facilities, surgery centers, clinics, and other healthcare providers across the country. GPOs help secure access to medical products for their provider members under competitive terms, providing savings for patients, providers, Medicare, Medicaid, and taxpayers.[2] Moreover, health systems, physician offices and other providers often rely on GPOs for services well beyond supply contracting and procurement. GPOs' wide-ranging services include providing broad clinical feedback and supply chain analytics, which are especially important for providers in rural and underserved areas. Individual practices and community hospitals, in particular, often do not have the resources, scale, and expertise to do this work themselves. The use of GPOs by providers and suppliers alike is completely voluntary – no provider is required to join a GPO program, and all participants choose to do so due to the efficiencies and other value that GPOs deliver to the healthcare system. Similarly, no supplier is required to contract with a GPO and many choose to sell their products directly to providers.

Both independent and industry-funded studies confirm the effectiveness and tremendous value of GPOs to healthcare providers and the healthcare system at large, finding that GPOs deliver annual cost savings of 12-18% across the entire medical supply portfolio.[3] [4] One report estimated that GPOs will reduce healthcare spending by up to $456.6 billion between 2017 and 2026.[5] Specific to government-sponsored health plans, GPOs were projected to generate $116.3 billion in Medicare cost savings and $90.1 billion in Medicaid cost savings over that timeframe.[6] Importantly, GPOs also enable rural and other smaller providers to obtain critical supplies at competitive value commensurate with large providers, allowing healthcare providers of all sizes to focus on their core mission: providing first-class patient care.

Meanwhile, the fees GPOs earn are minimal compared to the value delivered. A U.S. Government Accountability Office (GAO) report found that the average administrative fee percentage paid under all GPO supplier contracts is between 1.22%-2.25%.[7] Moreover, the administrative fee is calculated based

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[1] Footnote 1 of the joint RFI offers the following definition of "GPO,": "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." While clearly not intended, the structure of the definition may have confused some commenters into perceiving that GPOs themselves distribute or sell such pharmaceuticals or supplies to healthcare providers. By this comment letter, HSCA hopes to clarify the role of traditional healthcare GPOs as distinct from other entities in the pharmaceutical supply chain such as wholesalers and PBMs.

[2] Healthcare providers that elect to participate in a GPO program are interchangeably referred to as "members," "participants," or "customers" of the GPO that are eligible to make purchases pursuant to the terms of applicable GPO contracts with suppliers.

[3] Lawton Robert Burns and J Andrew Lee, "Hospital purchasing alliances: utilization, services, and performance," *Health Care Management Review* 33, 3 (July 1, 2008): 203-15, https://doi.org/10.1097/01.hmr.0000324906.04025.33

[4] Allen Dobson and Joan DaVanzo, "A 2018 Update of Cost Savings and Marketplace Analysis of the Health Care Group Purchasing Industry," April 2019, https://www.supplychainassociation.org/wp-content/uploads/2019/05/HSCA-Group-Purchasing-Organizations-Report-FINAL.pdf.

[5] Ibid.

[6] Ibid.

[7] U.S. Government Accountability Office, "Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices, Report to the Ranking Member, Committee on Finance, U.S. Senate," September 27, 2010, https://www.gao.gov/assets/a308834.html.

on the purchase price paid for the contracted product or service (i.e., the discounted price paid by the provider-purchasers under the GPO contract), not list price or other inflated amount. Former FTC Chair Jon Leibowitz has affirmed the benefits of the GPO model, finding, among other things, that GPOs help lower costs for providers, patients, and taxpayers, and that the GPO administrative fee model is the most economically efficient model for the supply chain.[8]

There are a number of misconceptions and misunderstandings about what GPOs do in support of the healthcare supply chain and procurement of pharmaceuticals, in particular. We are pleased to offer the following key clarifications --

Traditional healthcare GPOs do:

- **Negotiate fair deals.** GPOs negotiate voluntary contracts with manufacturers and distributors of products and services desired by healthcare provider members that have more competitive pricing, terms, and conditions than those providers may be able to secure on their own.

- **Drive efficiencies in the healthcare marketplace.** GPO transactional services eliminate the need for the many thousands of healthcare providers and manufacturers of medical supplies to repeatedly negotiate with each other, instead allowing them to focus their time and effort on providing quality care and products in service of patients.

- **Engage providers in all bidding and contracting activities.** GPOs involve their provider members in every step of the contracting process, ensuring that all appropriate potential suppliers are invited, considered, and/or included in a bidding process, and that any ultimate contract awards are designed to meet the providers' needs.

- **Serve as an essential resource to rural, smaller and niche healthcare providers.** GPOs enable these providers – a significant number of which are under intense financial strain – to access competitive pricing and favorable terms on essential supplies on par with their larger healthcare counterparts.

- **Act with transparency and integrity.** GPOs provide transparency reporting to their members, at least annually, about administrative or other fees collected from GPO-contracted suppliers. In addition, traditional healthcare GPOs participate in and abide by a comprehensive code of ethics established and managed by the Healthcare Group Purchasing Industry Initiative (HGPII).

Traditional healthcare GPOs do not:

- **Place orders for products on behalf of healthcare provider members/buyers.** Rather, providers voluntarily place their own orders either directly with the manufacturers or with distributors/wholesalers, on the terms and pricing negotiated by the GPO where available. GPOs do not dictate their members' product purchases or volumes.

[8] Daniel O'Brien, Jon Leibowitz, and Russell Anello, "Group Purchasing Organizations: How GPOs Reduce Healthcare Costs and Why Changing Their Funding Mechanism Would Raise Costs," *The Antitrust Source*, June 2017, https://www.davispolk.com/sites/default/files/antitrust_source_how_group_purchasing_organizations_reduce_leibowitz_anello.pdf.

- **Take title to products or manage distribution of products ordered by provider members.** Product orders are placed with and fulfilled by either direct shipping/delivery from manufacturers or with and from wholesalers/distributors.

- **Dictate the prices charged or production volumes generated by manufacturers.** GPOs seek to negotiate fair prices with manufacturers for their products and, through GPO contracts, provide a degree of certainty and predictability of demand to inform the manufacturers' production levels. Ultimately, however, the prices offered by manufacturers as part of an GPO RFP process, as well as their actual production capacities, are entirely within the manufacturers' control. GPOs also do not dictate whether a manufacturer should increase, decrease, or cease production of a particular product, as those decisions rest entirely with the manufacturer.

- **Impose or mandate contracts or purchase obligations on providers.** GPO contracting processes are conducted in close collaboration with and approvals by their provider members. GPOs do not dictate or impose contracts or purchase requirements on them. If and to the extent there may be more advantageous terms, such as additional discounts, available to provider members willing to commit to certain purchase volumes with a particular supplier, such commitments are entirely voluntary.

- **Earn or retain rebates based on provider member purchases.** Unlike, for example, PBMs that are paid rebates from manufacturers based on pharmaceutical purchases in their own right, any rebates that suppliers remit to GPOs based on purchases by their provider members are 100% passed through by the GPOs to those provider members. GPOs do not retain any portion of provider-earned rebates.

- **Play a significant role in the volume or prices of products produced for, or fulfilled by, retail pharmacies, such as oral solid attention deficit hyperactive disorder (ADHD) medicines.** GPO contracts pertain to purchases by healthcare providers used in the site of care settings (e.g., hospitals, physician offices, urgent care). While some GPOs may have retail pharmacy members, only a de minimis amount of retail pharmacy drug purchases are made through GPO contracts. Rather, wholesalers/distributors and PBMs are responsible for almost all of the retail pharmacy drug purchases and dispensations. Indeed, it is important to note that products in the marketplace that are currently in short supply, like Amoxicillin, other oral solids and liquids, Adderall, and other medications used to treat ADHD are predominantly sourced in the retail marketplace completely outside of GPO contracts.

<u>The Traditional Healthcare GPO Model and Value Proposition.</u>

The traditional healthcare GPO model is voluntary, flexible, and clinically driven. These GPOs work in close collaboration with healthcare providers to maintain competitive sourcing practices and contract award decisions. GPOs take a comprehensive approach to sourcing and contracting that not only accounts for the competitive price offered, but also non-financial criteria such as the reliability and stability of supply. Evaluation criteria vary based on product category and frequently non-financial criteria take priority over price. GPOs recognize that market conditions change and, when they do, GPOs work with suppliers to adjust accordingly. GPOs work diligently to ensure member hospitals and providers can access the products they need to care for their patients most effectively.

GPO contract award decisions are made pursuant to a competitive bidding process with input and direction from advisory boards of their member providers. RFPs are distributed and responsive proposals from suppliers electing to participate are reviewed and analyzed. GPOs and the member advisory boards carefully evaluate drug suppliers on the consistency of product availability, fill rates, recall frequency and management, disaster preparedness, secondary supply lines, and manufacturing transparency including available quality records. Depending on the nature of the product or service category, the advisory boards primarily consist of healthcare member professionals, such as physicians, surgeons, pharmacists, nurses, and other clinicians, procurement and supply chain professionals, or others. The clinical advisory boards are instrumental to ensuring that GPOs pursue contracts with suppliers offering the greatest value proposition for the members and, ultimately, the patients they serve. With respect to pharmaceutical contracts specifically, the stability of supply is a critical element.

Healthcare GPOs provide significant cost-savings for providers and payors alike, including Medicare and Medicaid. GPOs reduce transaction costs for providers and secure lower prices by negotiating discounts from suppliers.[9] The reduction in transaction costs benefits suppliers as well, by consolidating sourcing and contracting efforts while facilitating efficient and predictable transaction volumes for them.

Healthcare GPOs offer comprehensive transparency to their provider members. GPO members have access to the contracts GPOs enter into with suppliers, and each has full visibility into any administrative fees earned by the GPO on their purchases in strict compliance with the GPO Safe Harbor to the Federal Anti-Kickback Statute.[10] Additionally, all non-governmental HSCA member GPOs participate in the Healthcare Group Purchasing Industry Initiative (HGPII), a voluntary industry governance organization that annually reviews and publicly reports on GPO practices concerning administrative fees, additional sources of income, and other ethics and compliance issues.[11]

Traditional Healthcare GPOs are Critical Resources for Small and Rural Healthcare Providers.

Due to persistent financial pressures including increasing labor costs and challenges with payors, American hospitals – particularly those in rural areas – are in a precarious posture that threatens their ability to stay open in their communities. According to a report from the Center for Healthcare Quality and Payment Reform, "all but seven states have at least one rural hospital at immediate risk of shutting down."[12] Over 600 rural hospitals – around 30% of all rural hospitals across the country – are at risk of closing in the near future.[13] GPOs enable small and rural healthcare providers, which often lack the transactional experience and resources, to access competitive pricing and favorable terms on essential supplies on par with their larger healthcare counterparts, thus allowing them to focus on providing care as their top priority. In fact, according to Definitive Healthcare, of the nearly 2,600 rural and critical access hospitals in the United States, 95% have a designated primary GPO, demonstrating the value that the GPO industry brings to these critical institutions.

[9] Ibid.
[10] 42 U.S.C. §1320a-7b(b)(3)(c); 42 C.F.R. §1001.952(j).
[11] See Healthcare Group Purchasing Industry Initiative, www.hgpii.com .
[12] "The Crisis in Rural Health Care," Saving Rural Hospitals, https://ruralhospitals.chqpr.org/.
[13] Marcus Robertson, "631 Hospitals at Risk of Closure, State by State," *Becker's Hospital Review*, January 3, 2023, www.beckershospitalreview.com/finance/631-hospitals-at-risk-of-closure-state-by-state.html?utm_medium=email&utm_content=newsletter.

Traditional Healthcare GPOs are Not PBMs or Wholesalers.

In the pharmaceutical supply area, it is important to recognize that traditional healthcare GPOs are entirely distinct from pharmacy benefit managers (PBMs), PBM-operated rebate aggregators (sometimes presented as "GPOs" and, as such, erroneously confused with the provider-facing healthcare GPOs that HSCA represents), and large retail buying groups such as wholesalers/distributors. Differentiating traditional healthcare GPOs is that they are provider-aligned, serve healthcare providers, are transparent with their customers, do not take possession of or title to product, and are net-price driven. GPOs primarily negotiate point-of-sale price reductions, and if and to the extent there are any post-sale rebates earned on member purchases, those rebates are passed entirely through to the providers that earn them. Flexibility for providers and suppliers is integral to the GPO business model and, importantly, actual pharmaceutical purchases are made by the providers, not GPOs. The interests of GPOs are aligned with their healthcare provider members and, indeed, many GPOs are owned by providers.

In contrast, PBMs work primarily in the retail prescription market with health insurance companies and plan sponsors, and PBM-operated "GPOs" aggregate rebates owed to the PBMs themselves. Increasingly these market participants are vertically integrated, often with a payor, giving them significant influence in the pharmaceutical supply chain, as well as the ability to collect and retain incentives beyond administrative fees.[14] Meanwhile, pharmaceutical wholesalers/distributors – also known as "buying groups" or "retail sourcing organizations" – likewise aggregate purchasing and compete in the retail pharmaceutical market, and do directly purchase and take possession of products themselves. Neither represent the provider segment like traditional healthcare GPOs, nor are they subject to the transparency requirements applicable to healthcare GPOs.

Traditional Healthcare GPO Dynamics in the Marketplace.

Traditional healthcare GPOs help create a fair, open, and competitive marketplace and compete for business on a variety of factors including, but not limited to, supplier pricing and other contract terms, breadth of product portfolio, supply chain and clinical analytical assistance, and customer service. In turn, these GPOs make contract award decisions based on member preferences through advisory board reviews, accounting for aggregate supply volumes needed by the GPO members and the length of contracts. An analysis of the traditional healthcare GPO model by former FTC Chair Jon Leibowitz reaffirmed the benefits of the GPO model, finding, among other things, that there is vigorous competition among GPOs, that competition among GPOs ultimately helps lower costs for providers, patients, and taxpayers, and that the GPO supplier-administrative fee model is the most economically efficient model for the supply chain.[15]

GPOs Do Not Possess Market Power to Foreclose Competition

A primary service of GPOs is to negotiate competitive pricing for their provider members, which ultimately contributes to more sustainable costs of care for patients. While GPO transactional support on behalf of their provider members helps enable them to achieve lower prices, these GPOs do not possess power to drive supplier prices and output below competitive levels.[16]

[14] For additional information on the differences between traditional healthcare GPOs and PBMs, please visit HSCA's website at https://www.supplychainassociation.org/wp-content/uploads/2019/01/HSCA-GPO-and-PBM-Comparison.pdf

[15] O'Brien, *et al*. (fn 8)

[16] HSCA previously submitted a letter dated February 27, 2023, to Chair Khan, Commissioner Slaughter and Commissioner Bedoya, which addressed this and other topics.

Importantly, healthcare providers can and do purchase medical products, including pharmaceuticals, through a variety of direct and distributed channels, which may or may not involve one or more GPO relationship. Competition among GPOs, and between GPOs and other non-GPO buying channels, is fierce.

The marketplace for GPO services alone is diversified and highly competitive across hundreds of traditional healthcare GPOs in the United States. Definitive Healthcare reports data on 150 GPOs – likely a conservative estimate – with eighty considered regional GPOs or "regional purchasing coalitions," and seventy national GPOs.[17] [18] In 2020, the market share percentage of total healthcare spend through the contract portfolios of the three largest of those GPOs was 20.7%, 12.6%, and 8.2%, respectively, each well below any share that would signal any disproportionate market power in purchasing channels.[19] [20] Meanwhile, there is significant fluidity for providers using GPOs. Healthcare providers typically engage in primary GPO membership arrangements following a competitive procurement processes with multiple GPO bidders. Rebidding occurs frequently, and incumbent GPOs are often unseated. In addition, most healthcare providers maintain multiple national, regional and/or specialty GPO memberships, varying their purchasing among GPO contract portfolios. The volume of provider purchases directly from suppliers outside of those GPO contract portfolios is also significant – a 2020 analysis showed that a full 30% of hospital supply spend was pursuant to direct (non-GPO) contracts and non-contract purchases.[21] [22]

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[17] Lawton Robert Burns, *The Healthcare Value Chain: Demystifying the Role of GPOs and PBMs* (Palgrave Macmillan, 2022) , 93. Professor Burns cites an estimate that there were 567 GPO enterprises in 2020.

[18] "Healthcare Analytics & Provider Data | Definitive Healthcare." www.definitivehc.com.

[19] *2022 Source Guide*. Healthcare Purchasing News, 2022.

[20] Notably, the FTC has also reviewed the GPO marketplace in connection with several HSR-reportable transactions in recent years, each of which have gone forward without challenge.

[21] Lawton Robert Burns and Allison D Briggs, "Hospital purchasing alliances: Ten years after," *Health Care Management Review* 45, 3 (July-September 2020): 186-195, https://faculty.wharton.upenn.edu/wp-content/uploads/2016/11/Hospital-purchasing-alliances_-Ten-years-after.pdf. https://journals.lww.com/hcmrjournal/Abstract/2020/07000/Hospital_purchasing_alliances__Ten_years_after.2.aspx

[22] HSCA is aware that various commenters have advanced inconsistent and conclusory assertions that the largest national healthcare GPOs "control" or "account for" 90% of the market for generic pharmaceuticals. **These assertions are inaccurate and unproven.** This misinformation appears due, at least in part, to unsubstantiated "opinions" as well as persistent confusion about the fundamental differences between wholesalers and GPOs, including the conflation of "buying groups" that actually purchase pharmaceuticals, with GPOs. Importantly, an HHS study on prescription drug spending found that, in 2021, $421B worth – or 69.8% -- of the total $603B spent on prescription drugs in the U.S. was spent in the retail setting, i.e., chain store pharmacies, mail order pharmacies, independent pharmacies and food store pharmacies. https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf. *As described elsewhere in this letter, unlike wholesalers/distributors, GPOs do not purchase pharmaceuticals and predominantly are not involved with supplies provided to retail pharmacies, among other things.*

This misinformation has unfortunately been repeated and gained increasing traction through a number of high-profile platforms and reporting media outlets. Noteworthy instances we have identified as sources of this misperception include the following:

1) Reference to a 90% figure appears to have first surfaced in a "Viewpoint" opinion piece published by the Journal of the American Medical Association (JAMA) on November 13, 2018, with the authors stating "collectively, the 4 largest GPOs in the United States account for 90% of the market for medical supplies." https://jamanetwork.com/JOURNALS/JAMA/ARTICLE-ABSTRACT/2708613. *The opinion piece authors provide no analysis or citation for their 90% figure concerning "medical supplies".* Nonetheless, later, in a 2019 report titled *Drug Shortages: Root Causes and Potential Solutions*, the U.S. Food and Drug Administration (FDA) cited the JAMA opinion piece as its source for asserting that "…GPOs have consolidated their market power, so that by 2018 the four largest GPOs accounted for about 90 percent of the market for medical supplies in the United States (Bruhn et al. 2018). As a

Finally, barriers to entry into providing GPO services are low. New GPO entrants can enter the market quickly once they have the organizational, contracting, and financial skills to engage in negotiations. Indeed, of the GPOs appearing on Definitive Healthcare, approximately twenty were established in the last two decades.

Simply put, GPOs operate in a market environment in which they face actual or potential competition from a significant number of other entities and purchasing channels.

GPO Contracting Processes Are Fair and Inclusive

GPO contracts with suppliers of healthcare products and services entirely voluntary and designed to meet provider needs, which are multi-faceted and, ultimately, patient-driven. In addition to securing reasonable prices, supplier contract award decisions are based on considerations such as consistency of product availability, fill rates, recall frequency and management, disaster preparedness, and redundancies and transparency in their manufacturing and quality, among other factors.

Core to GPO transactional services is the use of sophisticated product evaluation teams to help assess supplier options for their healthcare provider members. These teams are well positioned to identify alternatives if a dominant supplier attempts to exploit its market position, and they can utilize their negotiating expertise to secure contracts with a range of supplier alternatives as dictated by the interests of their provider members.[23]

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result, GPOs have been able to negotiate low prices, especially for multi-source generics." https://www.fda.gov/media/131130/download?attachment. *As such, an unsubstantiated reference to "90%" was then connected to an agency-authored narrative about multi-source generics.*

2) In his written testimony submitted to the House Energy and Commerce Subcommittee on Oversight and Investigations on May 9, 2023, the Chair of the API Innovation Center at Washington University in St. Louis, referenced his own study published April 21, 2023 purporting to "show that [pharmaceutical] price erosion . . . is further accelerated by the market consolidation of the number of drug wholesalers and group purchasing organizations." https://democrats-energycommerce.house.gov/sites/evo-subsites/democrats-energycommerce.house.gov/files/documents/Testimony_OI_Sardella_2023.05.11.pdf. *However, his April 2023 study does not reference or describe GPOs, but instead refers to wholesalers, stating there are "three buying groups [that] make 92% of the wholesale generic purchases in the U.S."* Likewise, the source cited for that data point – a March 21, 2022 letter submitted by the Association for Accessible Medicines (AAM) to the FTC – does not refer to GPOs but rather to three specific "pharmaceutical buying groups" that "consolidat[e] major wholesale and retail purchasers into a single entity for purchases of buying generic products from manufacturers" – specifically, Red Oak Sourcing, Walgreens Boots Alliance, and ClarusOne/McKesson – which AAM calculates "account for over 90% of the generic purchases". https://accessiblemeds.org/sites/default/files/2022-03/AAM-Public-Comments-RFI-Merger-Enforcement-Version-3-18-22.pdf

3) In his written testimony submitted to the House Energy and Commerce Subcommittee on Health on September 14, 2023, the CEO of AAM said, "[t]hree hospital/clinic group purchasing organizations (GPOs) control roughly 90 percent of all generic medicine purchasing for hospitals/clinics", this time citing as the source a white paper by the Commonwealth Fund, "The Impact of Pharmaceutical Wholesalers on U.S. Drug Spending." https://d1dth6e84htgma.cloudfront.net/David_Gaugh_Witness_Testimony_09_14_23_5caf7c1a77.pdf. *However, the cited white paper is not referring to GPOs (which it does not discuss at all), but rather the three major wholesalers*, stating "[a]bout 92 percent of prescription drugs in the United States are distributed through wholesalers, with three — AmerisourceBergen, Cardinal Health, and McKesson Corporation — accounting for more than 90 percent of wholesale drug distribution in the United States." https://www.commonwealthfund.org/publications/issue-briefs/2022/jul/impact-pharmaceutical-wholesalers-drug-spending.

[23] Burns and Briggs, 186-195 (fn 21).

Participation in GPO sourcing activities and supply contracts is voluntary for both healthcare providers and suppliers, and suppliers can and do transact business directly with providers outside of any GPO arrangement. That said, providers appreciate GPO contracts not only for the transactional efficiencies and advantageous terms they bring, but also because they result from GPO diligence during the sourcing and contracting process to ensure suppliers are committed to manufacturing products on a consistent basis, have strong supply chain features including high levels of safety stock, strong supply chain mapping, and supply chain redundancy. GPO relationships also encourage suppliers to offer broad supply lines, remain price competitive, and provide high-quality products.[24]

The suppliers are likewise well-informed and sophisticated participants in the supply chain. They may negotiate contracts with multiple GPOs, and ultimately they decide the pricing of their products offered through a GPO arrangement or other channels. For the vast majority of product and service categories, GPOs enter into contracts with multiple suppliers on a "dual-source" or "multi-source" basis, providing flexibility within the GPO portfolio for provider-members to choose among alternate suppliers.[25] Meanwhile, much less frequently, and where the GPO's provider members feel it is appropriate, GPOs may enter a "sole-source" agreement with a particular supplier for a specific product or service category – such that the GPO commits to maintain a supplier-dedicated agreement in its portfolio for a limited term – if the providers conclude that it would substantially increase the value proposition. While, contrary to a common misconception, such contracts do not prohibit or restrict the ability of providers to purchase outside of those agreements, they do provide suppliers with increased predictability in demand, enabling them in turn to make commitments to upstream suppliers of product components and inputs, as well as to invest in capital upgrades and customer service resources.

GPO sole-source contracting in particular is not of a prevalence or nature to result in substantial customer foreclosure so as to prevent other suppliers from entering or remaining in the market, especially given the sophistication and large number of buyers. In such a market, a supplier would likely find it impossible to preclude any competitor, large or small, from selling to a large number of willing provider-buyers.[26] Moreover, no supplier has informed a HSCA member GPO that a drug or product shortage was due to the supplier either being awarded or not awarded a GPO contract.

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[24] See e.g., Amphastar Pharmaceuticals, Inc., Form 10-K for Fiscal Year Ended December 31, 2022, U.S. Securities and Exchange Commission, 37 https://www.sec.gov/ix?doc=/Archives/edgar/data/0001297184/000129718423000019/amph-20221231x10k.htm ("Maintaining our strong relationships with these group purchasing organizations will require us to continue to be a reliable supplier, offer a broad product line, remain price competitive, comply with FDA regulations and provide high-quality products.")

[25] Healthcare Group Purchasing Industry Initiative, "Sixteenth Annual Report to the Public," 2022, 11-12, https://hgpii.com/wp-content/uploads/2022/02/HGPII-16th-Annual-Report-Member-Final.pdf ("[We] have found that multisource contracts remain the industry preference where products or services are available from multiple vendors that are able to conform to standards. Single or sole source contracts represent very few current GPO offerings, and a very small percentage of GPO sales. Most of the examples of single source GPO contracts represent products for which there is no generic equivalent or, for which there is no competing vendor. Among those GPOs that permit single source contracts in other situations, contracting decisions are the result of express client preferences and needs.").

[26] See HSCA's letter dated February 27, 2023, to Chair Khan, et al.

Traditional Healthcare GPOs Work to Prevent and Mitigate Drug Shortages.

The causes of drug shortages are complex and multifaceted. The FDA identifies manufacturing quality control issues as the primary cause, along with production delays, lack of raw materials, and manufacturer business decisions to discontinue products.[27] [28] GPOs recognize the cost and impact of drug shortages on their member hospitals and the patients they serve, and are leaders in working to prevent and mitigate drug shortages – not cause them.

Notably, at the outset, healthcare GPO activities cannot be considered a contributing factor towards the shortage of nearly half of the drugs identified by the U.S. Food and Drug Administration (FDA) by their very nature. Specifically, of the 121 molecules identified by the FDA as "currently in shortage" as of February 17, 2024, 53 are either (i) non-injectable products used in the retail setting (e.g. amoxicillin, Adderall), (ii) novel, branded injectable medications used for chronic diseases outside hospitals and health systems, or (iii) medications for which only medication importation is available (e.g., cefotaxime); and an additional five medications have a market share of under 50% attributed to the hospital and healthcare provider market that traditional healthcare GPOs serve.[29] Those ~48% of FDA-identified shortage drugs are drugs for which (i) GPOs do not contract, (ii) there is inherently no manufacturer competition to facilitate negotiations (i.e., branded/non-generic medications), and/or (iii) sales pursuant to GPO contracts represent only a small portion of the market share (e.g. retail vs. primary care setting).

As for those products procured by healthcare provider members for use in a site of care, HSCA and its member GPOs are committed to collaborating with healthcare providers and suppliers to bolster the resiliency of the healthcare supply chain so that providers have consistent access to the drugs, products, and devices they need to treat their patients. Indeed, shortages are antithetical to the GPO model – without sufficient products, suppliers, or competition, GPOs are unable to provide their services.

Examples of HSCA-member GPO activities in support of a resilient drug supply include:

- GPOs track available data on shortages and raw materials, including active pharmaceutical ingredients (API), on a global scale to anticipate possible supply disruptions.

- GPOs identify and help bring to market additional manufacturers of at-risk drugs, endeavoring to ensure that there are auxiliary suppliers of essential medications and products.

- GPOs request manufacturers to provide comprehensive product disruption information during their supplier evaluation process, including requesting copies of any FDA "Notice of Inspectional Observations" issued for potential manufacturing deficiencies (FDA Form 483s), and consider any FDA Warning Letters indicating potential enforcement actions against a manufacturer.

[27] U.S. Food and Drug Administration., "Frequently Asked Questions about Drug Shortages," October 11, 2023, www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages .
[28] See, e.g., Eagle Pharmaceuticals, Inc., Form 10-K for Fiscal Year Ended December 31, 2017, U.S. Securities and Exchange Commission, 47, https://investor.eagleus.com/node/6546/html ("Quality problems in manufacturing are linked to a majority of shortages of sterile injectable drugs. Some of the largest manufacturers of sterile injectable drugs have had serious quality problems leading to the temporary voluntary closure or renovations of major production facilities.").
[29] IQVIA SMART system, www.customerportal.iqvia.com (subscription required), accessed February 27, 2024.

- GPOs maintain close contact with manufacturers' senior representatives when issues with certain products arise, in order to determine the potential impact on product availability and identify alternative manufacturers for additional agreements to help mitigate any such potential shortages.

- GPOs consult other available resources for additional information to strengthen the supply chain, including the FDA's Center for Drug Evaluation and Research (CDER) Quality Management and Maturity (QMM) program, which asks drug manufacturers to provide information on the quality of manufacturing facilities and areas where they need improvement.[30]

In addition, HSCA member GPOs have also developed innovative programs that work to prevent and minimize the impact of shortages. For instance, one HSCA member GPO developed a Supply Interruption Mitigation Strategies (SIMS) program to help protect against supply interruptions and sudden and often severe price increases.[31] The SIMS program maps out supply chains and identifies the optimal supply chain for mission critical products, including manufacturing and API redundancies, geographic diversification, and the quality profile of the manufacturers supplying critical products along the supply chain.

Another HSCA member GPO has similarly created a drug shortage mitigation program, by which it works with suppliers to ensure availability of onshore buffer inventory of essential medications critical to clinicians' ability to provide immediate patient care. The GPO has worked with both providers and suppliers to create a consistent demand, increase availability of essential medications, and improve supply chain resiliency through transparency, accountability and commitment to supply.

Yet another HSCA member GPO that specializes in serving children's hospital providers has implemented a predictive approach to solving and/or mitigating the patient impact of pediatric medication shortages. Given the unique nature of drugs intended for children – including the risks of handling, niche formulations and dosing, and specialized delivery mechanisms (e.g., pediatric-sized syringes) – there are fewer manufacturers and a less resilient supply chain. Among other things, the GPO has established a collaborate industry framework to inform the testing and production of a sufficient volume of compounds and medications essential to treating children with full protocols, including concentrated electrolytes for total parenteral nutrition (TPN); concentrated bulk albuterol, a staple in children's hospitals to provide emergency support for kids with asthma; and key pediatric chemotherapies.

<u>Traditional Healthcare GPOs Support Government Efforts to Increase Supply Chain Resiliency and Help Prevent Drug Shortages.</u>

HSCA and its member GPOs are proud participants in a variety of government-led and public-private initiatives designed to prevent and mitigate drug and other shortages. Examples of HSCA and GPO advocacy efforts include:

[30] U.S. Food and Drug Administration, "CDER Quality Management Maturity," November 10, 2022, www.fda.gov/drugs/pharmaceutical-quality-resources/cder-quality-management-maturity.
[31] "HealthTrust's SIMS Contracting Strategy Addresses Drug Shortages," *The Source* (Q3 2019) , https://healthtrustpg.com/thesource/pharmacy/drug-shortages/healthtrusts-sims-program-addresses-drug-shortages/.

- GPOs engage with the FDA and the agency's Drug Shortage Task Force, the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Strategic National Stockpile (SNS) and numerous other government and industry partners to support a healthy supply chain.

- GPOs have provided input and support for federal proposals to curb drug and product shortages, including the accelerated approval of generic products, the QMM process, and the strategic development of new supply sources.

- HSCA convened a Drug Shortage Working Group comprising leading healthcare provider organizations to develop policy recommendations to help prevent and address drug shortages, ensure stable supply of critical medications, and support supply chain resiliency. The working group directly engaged with senior FDA officials to share information and assess potential solutions.

- In the wake of the COVID-19 public health crisis, traditional healthcare GPOs advocated for policies to reduce shortages, among them expedited approval processes for products with unhealthy markets, requirements for manufacturer contingency plans in the event of an emergency and requirements for suppliers to give advance notice before discontinuing production. These GPOs also convened national healthcare supply chain public-private workgroups during the pandemic focused on helping identify sources of critical medications and devices throughout the nation and helping providers in need access them.

HSCA and its member GPOs respectfully offer the following specific policy recommendations to lawmakers and implementing agencies to help prevent and mitigate ongoing drug shortages:

- **Invest in quality and building secondary supply lines.** HSCA recommends incentivizing not just production, but also investment in quality and capacity, including the addition of secondary supply lines and having alternate or backup sources of API, to support long-term access to generic medications.

- **Create incentives to increase domestic manufacturing.** HSCA recommends that any incentives related to domestic manufacturing be tied to quality and the amount of product sold in the U.S. For incentives to tangibly impact pricing dynamics, they must align with the quality products being made *and* sold in the U.S.

- **Refine authority related to the Strategic National Stockpile's (SNS) ability to enter into vendor contracts.** HSCA encourages refining the authority pertaining to the Fiscal year Consolidated Appropriations Act (P.L. 117-328), which authorized the Strategic National Stockpile (SNS) to enter into contracts to assist with the rotation of soon-to-be expired products so supply chain stakeholders can work collaboratively with agency officials to help identify when and where product should be released.

- **Maintain and/or require buffer inventory.** To increase critical access to drugs, HSCA recommends that the federal government, through the Administration for Strategic Preparedness and Response (ASPR) and SNS, create, maintain, and/or require buffer inventory for critical medications and devices.

- **Increase transparency on buffer inventories.** HSCA recommends transparency regarding buffer inventories and that input from GPOs and other private industry stakeholders be used to determine which drugs, and if possible, which products, should be considered for buffer inventory.

- **Fund and implement FDA's QMM program.** HSCA recommends fully funding FDA's QMM program and require manufacturer participation and implementation as soon as possible. HSCA further recommends that FDA share its QMM ratings with appropriate supply chain stakeholders, including GPOs, to best inform purchasing decisions.

- **Increase ongoing visibility into manufacturing locations and API sources.** HSCA recommends requiring manufacturers to include on their package inserts and boxes the finished product manufacturing location, including for contract manufacturers, and API source(s) on all products.

- **Increase facility inspections.** HSCA recommends increasing funding for, and the number of, announced and unannounced FDA inspections. HSCA further recommends that the FDA begin unannounced foreign inspections for API supplies and drug product manufacturers, and that inspections occur at the same time interval for all FDA-registered facilities regardless of location.

- **Adjust the FDA drug shortages list for pediatric medications and regional shortages**. HSCA recommends that the FDA's drug shortages list be adjusted to provide a timely and accurate accounting of pediatric populations and pediatric drug formulations, including the potential for regional shortages.

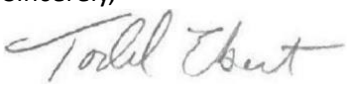
- **Encourage increased production of at-risk pediatric medications.** HSCA recommends reducing the risk of pediatric drug and supply shortages by encouraging "readiness to supply," or proactive shortage mitigation plans and/or competition in production of pediatric products that are often under-resourced.

* * * * *

We appreciate the opportunity to provide you with our comments and recommendations, and appreciate the FTC and HHS's willingness to learn about the GPO industry, our members' role in the healthcare supply chain, and how HSCA and our member GPOs work to prevent and mitigate drug shortages. We hope this has been helpful to describe the critical role GPOs play in making the healthcare system operate more efficiently by providing valuable services to healthcare providers and supplier partners in their sourcing and contracting practices and other areas. GPO services not only help reduce healthcare costs for providers and payors and support the provision of high-quality and lower-cost care to patients, but also enable consistency and predictability in the supply chain. We hope this information has also been helpful to clarify how the role of traditional healthcare GPOs differs from others in the pharmaceutical supply chain, such as PBMs and wholesalers/distributors. We look forward to continuing to serve as a resource to your agencies and all stakeholders as we all work together to continue improving the healthcare system.

Please do not hesitate to contact Allen Hamilton, Executive Director at HSCA, if we can be a resource on this issue moving forward. He can be reached at (202) 629-5833 and ahamilton@supplychainassociation.org.

Sincerely,



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