December 19, 2023

The Honorable Ron Wyden
Chairman
Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate
Washington, DC 20510

Re: Statement for the Record on the Senate Finance Committee's *"Drug Shortages: Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective"* Hearing on December 5, 2023

Dear Chairman Wyden and Ranking Member Crapo:

On behalf of the Healthcare Supply Chain Association (HSCA), which represents the nation's leading healthcare group purchasing organizations (GPOs), we appreciate the opportunity to provide a statement for the record regarding the December 5, 2023, hearing on examining supply challenges, impacts, and policy solutions for drug shortages. HSCA supports your continued efforts to address this pressing problem, and we look forward to continuing to work with you to determine long-term solutions to prevent and mitigate drug shortages and preserve access to high-quality care.

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 the sourcing and contracting partners to hospitals, long-term care facilities, surgery centers, clinics, and other healthcare providers across the country. GPOs secure high-quality medical products at fair prices for the benefit of patients, providers, Medicare, Medicaid, and taxpayers. Both independent and industry funded studies confirm the effectiveness and tremendous value of GPOs, finding that GPOs deliver annual cost savings of 12-18%.[1] [2] GPOs allow smaller providers to obtain critical supplies at the same value as large providers while allowing all healthcare providers to focus on their core mission: providing first-class patient care.

The GPO Business Model and Value Proposition.

The GPO business model is voluntary, flexible, and clinically driven. We work in close collaboration with our member hospitals and healthcare providers to develop sourcing policies and contract award decisions. GPOs take a comprehensive approach to sourcing and contracting that not only accounts for the competitive price offered, but also the quality, reliability, and stability of supply. We recognize that market conditions change, and when they do, GPOs work with suppliers to adjust contracts. GPOs work

[1] Burns, Lawton R, and J Andrew Lee. "Hospital purchasing alliances: utilization, services, and performance." *Health care management review* vol. 33, no. 3, 2008, pp.203-15 2008: 203-15. doi:10.1097/01.HMR.0000324906.04025.33
[2] Dobson, Allen, and Joan DaVanzo, "A 2018 Update of Cost Savings and Marketplace Analysis of the Health Care Group Purchasing Industry," Dobson DaVanzo & Associates, LLC, Apr. 2019.

diligently to ensure member hospitals and providers can select the products they need to care for their communities and patients most efficiently and provide clinical resources across their network of providers.

American hospitals are continuing to operate at razor thin margins and face an increasing number of closures, particularly among small and rural hospitals. GPOs allow these small and rural healthcare providers – who often lack the negotiating power to access competitive pricing for essential supplies – to take advantage of the same efficiencies and discounts as large providers, enabling them to focus on providing necessary care to their communities.

Health systems and independent physician offices often depend on GPOs for much more than their ability to collectively aggregate purchasing power. GPOs provide a range of services, including broad clinical feedback and providing supply chain analytics, which are especially important in rural and underserved areas. Individual practices and community hospitals do not have the resources, scale, and expertise to perform themselves.

The Scope and Impact of Drug Shortages.

Drug shortages place significant strain on hospitals, health systems, healthcare providers, and their patients. In 2022, the University of Utah Drug Information Service (UUDIS) identified a total of 160 national drug shortages. This figure is likely an underestimate, however, as many shortages go unreported and may occur in smaller geographic areas. A survey of manufacturers by UUDIS offered insight into the causes of drug shortages. More than half of those surveyed (56%) either did not know the cause of the shortage or would not provide this information. Those manufacturers that did respond cited supply/demand (19%), manufacturing (18%), business decisions (5%), regulatory issues (1%), and raw material issues (1%) as reasons behind shortages.

The U.S. Food and Drug Administration (FDA) identifies manufacturing quality control issues as the primary cause of drug shortages, along with production delays, lack of raw materials, and manufacturer business decisions to discontinue products. HSCA and its member GPOs are committed to collaborating with healthcare providers and suppliers to bolster the resiliency of the healthcare supply chain and to ensure that patients and providers have consistent access to the drugs, products, and devices they need.

GPOs Take Steps to Prevent and Mitigate Drug Shortages.

Despite some limitations on existing data, GPOs track all available data on shortages and raw materials, including active pharmaceutical ingredients (API). GPOs track this data on a global scale to anticipate possible supply disruptions and to provide suppliers with notice to plan for production capability. GPOs also identify and help bring to market additional manufacturers of at-risk drugs, ensuring that there are auxiliary suppliers of essential medications and products.

GPOs routinely evaluate drug suppliers on the consistency of product availability, fill rates, recall frequency and management, disaster preparedness, secondary supply lines, and manufacturing transparency. GPOs recognize and reward quality while encouraging a healthy market, and when shortages do occur, GPOs identify and support alternative sources and clinically appropriate substitutes.

GPOs recognize the cost and impact of drug shortages on their member hospitals and the patients they serve, and we are leaders in working to prevent and mitigate drug shortages. Every HSCA member GPO

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has innovative programs that are operating effectively to prevent and minimize the impact of shortages. The GPO business model creates a vigorously competitive and healthy market among GPOs and suppliers, and competition among GPOs is essential to preventing drug shortages. Shortages are antithetical to the GPO model, as without sufficient products, suppliers, or competition, GPOs are unable to provide their services.

Given our unique line of sight into the healthcare supply chain, HSCA and its member GPOs respectfully offer the following recommendations and comments to the Committee:

Re: Proposed policy solutions to prevent and mitigate drug shortages.

We understand that solving the ongoing drug shortage crisis is a complex task. HSCA proposes the following recommendations to help prevent and mitigate drug shortages, several of which build on existing congressional authorities:

Investing 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.

Creating incentives to increase domestic manufacturing. HSCA recommends that if Congress elects to create incentives related to domestic manufacturing that the incentives 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 congress to refine 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.

Increasing transparency. 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 Quality Management Maturity (QMM) program. HSCA recommends that Congress fully fund FDA's quality management maturity (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 that manufacturers be required to include on their package inserts and boxes the finished product manufacturing location, including for contract manufacturers, and API source(s) on all products.

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Increasing facility inspections. HSCA recommends that Congress increase funding for and encourage the FDA to increase the number of inspections. HSCA further recommends that Congress encourage FDA to begin unannounced foreign inspections for API supplies and drug product manufacturers.

Re: Consolidation among Group Purchasing Organizations (GPOs).

It is important to recognize that traditional healthcare GPOs are distinct entities from pharmacy benefit managers (PBMs), PBM rebate aggregators, and large retail buying groups such as wholesalers/distributors. Traditional provider-aligned healthcare GPOs serve healthcare providers, are fully transparent with their healthcare provider members, do not take title to product, do not participate in the Medicare Part D prescription drug program, and are net-price driven. GPOs negotiate point-of-sale price reductions, and any rebates members earn on their purchases are passed entirely through to them. Flexibility for providers and suppliers is integral to the GPO business model, and actual purchases are made by GPO member providers, not GPOs.

The interests of GPOs are completely aligned with their healthcare provider members, and some GPOs are owned by providers. Pharmacy benefit managers work primarily in the retail prescription market with health insurance and plan sponsors, and PBM-operated "GPOs" aggregate rebates. Pharmaceutical wholesalers/distributors – known as "buying groups" – also aggregate purchasing and compete in the drug supply market, but they do purchase and take possession of products and are not subject to the transparency requirements of traditional provider-aligned healthcare GPOs. GPOs operate in a vigorously competitive market and competition among GPOs is essential to preventing and mitigating drug shortages.

Additionally, it is worth noting that the statistic about GPO market share that Dr. Hernandez referenced in her written testimony is inaccurate and is sourced incorrectly.[3] [4] We believe the original source for this statistic actually refers to the market share of drug wholesalers, and not GPOs. There are hundreds of traditional healthcare GPOs in the United States. Definitive Healthcare reports data on 150 GPOs, which is likely a conservative estimate. Eighty of them are considered regional GPOs, or "regional purchasing coalitions," and seventy are national GPOs. The market share percentage of total spend through the contract portfolios of the seven largest GPOs in 2020 was between 54.1% and 60.5%, while the share of the three largest GPOs was 41.5%.

Many healthcare providers maintain membership with more than one GPO at a time and can shift their purchasing from one GPO contract portfolio to another. GPO contracts with healthcare providers are voluntary, and providers can shift to new areas, customers, or product focus, which helps maintain vigorous competition among GPOs. GPOs help create a fair, open, and competitive marketplace and compete for business on a variety of factors including, but not limited to, supplier product pricing, strength of supplier contract terms, breadth of contract portfolio, supply chain and clinical analytical assistance, and customer service.

We appreciate the opportunity to provide you with our comments and recommendations and appreciate the subcommittee's willingness to learn about the GPO industry, our role in the healthcare supply chain,

[3] Bruhn, William E., et al. "Group Purchasing Organizations, Health Care Costs, and Drug Shortages." JAMA, vol. 320, no. 18, 13 Nov. 2018, p. 1859, https://doi.org/10.1001/jama.2018.13604.
[4] Drug Shortages Task Force. "Drug Shortages: Root Causes and Potential Solutions." U.S. Food and Drug Administration, Oct. 2019.

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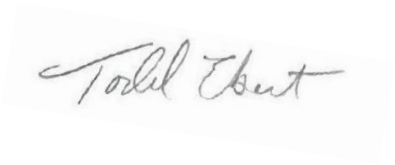
and how we work to prevent and mitigate drug shortages. We look forward to continuing to serve as a resource to Congress and all stakeholders as we all work to continue improving the healthcare system.

Please do not hesitate to contact me directly if HSCA can be a resource on this issue moving forward. I can be reached at (202) 629-5833 and tebert@supplychainassociation.org.

Sincerely,



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