HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

October 25, 2023

The Honorable Anna Eshoo
Ranking Member
Committee on Energy and Commerce
Subcommittee on Health
United States House of Representatives
Washington, DC 20515

Re: Questions for the Record on the House Energy and Commerce Committee's Subcommittee on Health *"Legislative Proposals to Prevent and Respond to Generic Drug Shortages"* Hearing on September 14, 2023

Dear Ranking Member Eshoo:

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 respond to the questions for the record regarding the September 14, 2023, hearing on legislative proposals to prevent and respond to generic drug shortages. We share your commitment to preventing and mitigating drug shortages, as initially outlined in our July 7, 2023, RFI response, our August 25, 2023, follow up comments to the *Stop Drug Shortages Act* discussion draft, and our appearance before the Subcommittee on Health at the September 14, 2023, hearing. 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 is voluntary, flexible, and clinically driven. GPOs work in close collaboration with 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

[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.

the competitive price offered, but also the quality, reliability, and stability of supply. GPOs recognize that market conditions change, and when they do work with suppliers to adjust contracts. GPOs work 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.

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 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[3] respectfully offer the following responses to your questions:

Re: Question 1*:* During the hearing, you indicated group purchasing organizations (GPOs) "take a comprehensive approach to sourcing and contracting" by assessing reliability of manufacturers. To elaborate on this, please provide which manufacturers of cisplatin and carboplatin were on the top three GPOs' contracts over the last five years. What was the compliance rate for each of these contracts?

Over the last five years, GPO member healthcare providers have awarded contracts for carboplatin and cisplatin to a diverse range of suppliers, including Teva, Pfizer, Fresenius Kabi, Accord, Alvogen, Sagent, and Eugia. HSCA member GPOs do not measure compliance for each individual product, but rather measure the compliance for the overall utilization of the contract or program which the product is a part of. Some GPOs may calculate compliance based on negotiated individual contracts, but that is up to the discretion of the GPO and their supplier partners.

GPO contracts are flexible, voluntary, and clinically driven. Because of this, providers may choose to purchase outside GPO contracts, and many do. It is important to note that the market share for each contracted product presentation differs each year, as providers may choose to purchase a contracted or non-contracted product based on both financial value and product availability.

Re: Question 2: During the hearing, you indicated GPOs lack transparency when making assessments around manufacturing quality. To elaborate on the extent of lack of transparency, please indicate which of the top five GPOs request unredacted 483's from manufacturers during RFI and the compliance rate with those requests. What are the factors that drive noncompliance? Similarly, which of the top 5 GPOs require unredacted 483's for contracted manufacturers during contract duration and what is the compliance rate with those requests?

The GPO sourcing and contracting process is an open and transparent process between GPOs and suppliers. HSCA member GPOs ask for as much information as possible from the manufacturers during the contracting process. However, it is not standard practice for HSCA member GPOs to request unredacted 483s from manufacturers during the RFI or contract cycle. If issues with certain products arise, HSCA member GPOs contact their supplier representatives to determine the impact on potential

[3] Group purchasing organization Premier, Inc. is not a part of HSCA and the above responses are not reflective of Premier, Inc.'s practices.

product availability and identify alternative manufacturers to contract with to mitigate any potential shortages.

There is currently no standard response that GPOs require from manufacturers when requesting information on 483s, making it difficult to establish whether there is a downstream impact on product availability. Many manufacturers state that compliance information is proprietary and confidential and do not share such information with their GPO partners. It is, however, standard practice for HSCA member GPOs to routinely check 483s published by the U.S. Food and Drug Administration (FDA), and request quality assurance reports given to manufacturers from the FDA and the U.S. Drug Enforcement Administration (DEA) if applicable. If a manufacturer receives a 483 and a Warning Letter, HSCA member GPOs may request the unredacted 483 and require manufacturers to provide remediations or potential plans of action to address any possible regulatory citations.

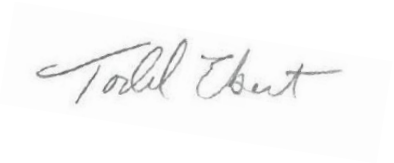
HSCA and its member GPOs recommend that when manufacturers provide GPOs with information on 483s, they provide a standard set of responses, so GPOs can measure the severity of 483s issued to determine product availability and whether alternative manufacturers should be sourced for the remainder of a contract if necessary. HSCA further recommends that the FDA improve its process regarding the completeness and timeliness of publishing unredacted 483s so GPOs and other industry stakeholders can better evaluate each situation both on a case-by-case basis and in real-time, as they occur.

Re: Question 3: If the 340B Drug Discount Program were to exclude generic sterile injectables, 340B entities would be able to contract with GPOs for the excluded drugs. What is the level of discounts you expect 340B hospitals would be able to obtain through GPOs if section 201 were to pass?

HSCA members are unable to anticipate possible savings that hospitals participating in the 340B Drug Discount Program may obtain through GPOs if section 201 of the *Stop Drug Shortages Act* discussion draft passes. There are multiple factors that could impact pricing strategies that may result in possible savings for 340B hospitals. Any discounts that become available would depend on the specific contract terms between the GPO and their 340B member hospital.

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