August 25, 2023

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Re: HSCA Comments on E&C Committee Discussion Draft *"Stop Drug Shortages Act"*

Dear Chair McMorris Rodgers:

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 feedback on the Committee's discussion draft, *Stop Drug Shortages Act*. We continue to share your goal of preventing and mitigating drug shortages, as initially outlined in our July 7, 2023, RFI response. We are concerned, however, that the GPO provisions in the subsequent legislative draft only add to the administrative burden facing America's healthcare providers. In fact, the legislative text is likely to exacerbate access challenges for critical medicines, particularly among small and rural hospitals, without addressing the current drug shortage crisis in a meaningful way.

Healthcare providers initially formed GPOs in the 1900s as an efficient means to aggregate purchasing volume, drive competition among suppliers, and reduce healthcare costs. Today, traditional healthcare GPOs are the sourcing and contracting partners to virtually all of America's 7,000+ hospitals, as well as the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers. The GPO business model – which includes voluntary participation by both providers and suppliers – has existed for more than 100 years and has resulted in billions of dollars in savings to hospitals and other healthcare providers, to the further benefit of 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]

HSCA members are committed to and practice transparency across the entire supply chain. While the GPO Safe Harbor (42 C.F.R. § 1001.952(j)) includes robust transparency and reporting requirements by GPOs to their members – and, upon request, to the government – all non-governmental HSCA member GPOs also voluntarily participate in the Healthcare Group Purchasing Industry Initiative (HGPII), an 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.

[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.

GPOs work in close collaboration with member hospitals and providers to develop sourcing policies and contract award decisions. GPOs provide significant value to providers in terms of the variety of products and services offered and take a comprehensive approach to sourcing and contracting that not only accounts for price, but also the quality, reliability, and stability of supply. 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. Indeed, shortages are antithetical to the GPO model, as without sufficient products, suppliers, or competition, GPOs are unable to provide their services.

We appreciate the Committee's recognition of the importance of expanding 503b compounding capabilities (outlined in Section 503), as this is critical for acute and non-acute healthcare providers, as well as pediatric and adult populations. GPOs contract with backup 503B compounders to augment the supply chain and mitigate drug shortages. We look forward to working with you on this provision, as well as incentives for quality control and increased manufacturing production.

Given GPO industry best practices and the stringent federal reporting requirements that are already in place, the GPO provisions of the discussion draft are unnecessarily duplicative and will not help address drug shortages. As a result, **HSCA and its members respectfully ask that sections 305, 307, and 401 of the *Stop Drug Shortages Act* be removed for the reasons articulated below**:

Re: Section 305: Requiring hospitals to report group purchasing remuneration under Medicare creates an unnecessary additional burden on hospitals, which already submit annual cost reports to Medicare.

Requiring hospitals to report remuneration from GPOs as a Condition for Participation in the Medicare program is unnecessary. Medicare-certified institutional providers already include any administrative fee share allocations in their annual cost reports to Medicare Administrative Contractors in compliance with the Discount Safe Harbor (42 C.F.R. § 1001.952(h)).

Raising the reporting requirement to an actual Condition of Participation would subject hospitals to a new level of sanctions and contradicts the Centers for Medicare and Medicaid Services (CMS) 2019 "Patients over Paperwork" initiative, as implemented under the Omnibus Burden Reductions final rule.[3] American hospitals operate at razor-thin margins and face an increasing number of closures, especially among small and rural hospitals. Creating additional burdensome reporting requirements will unnecessarily strain workforce resources when they can least afford it.

[3] "Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care." *Federal Register*, 30 Sept. 2019, www.federalregister.gov/documents/2019/09/30/2019-20736/medicare-and-medicaid-programs-regulatory-provisions-to-promote-program-efficiency-transparency-and.

Making remuneration information broadly available will also give rise to privacy and competition concerns. Moreover, the term "remuneration" is vague and broad, and is likely to be inconsistently applied.

If necessary, the government should focus on enforcing the current requirements pertaining to the reporting of discounts on cost reports versus implementing additional requirements, as the focus should be on patients, and not on paperwork.

Re: Section 307: Requiring clarification of Medicare average sales price payment methodology to provide a statutory definition for bona fide service fees will discourage suppliers and hospitals from working with GPOs and further increase drug shortages.

Section 307 narrows the statutory definition of bona fide service fees to exclude administrative fees paid to GPOs. Administrative fees paid to GPOs by manufacturers allow GPOs to perform services and drive efficiencies that would otherwise fall to the manufacturer, including enabling new product and manufacturer entry to the market, gaining insights into clinician preferences, negotiating and executing contracts governing a broad range of purchasers, and performing supply chain analytics.

Narrowing the statutory definition will discourage suppliers from working with GPOs because suppliers would have to include the GPO administrative fees in their product prices, which would then decrease their average sales price (ASP). Because it is less efficient for manufacturers to perform the services that GPOs provide, discouraging supplier-GPO collaboration in this area would drive up healthcare costs.

Although a key goal of the *Stop Drug Shortages Act* is to reduce drug shortages by increasing reimbursement fees for certain drug products, especially quality generic products, this section will have the unintended consequence of cutting Medicare payments to both physician and hospital-based providers. This will incentivize providers to not use a GPO, thus decreasing supply chain efficiencies and creating further fragmentation.

Health systems and independent physician offices depend on GPOs for the ability to collectively aggregate purchasing power. The other services that GPOs provide, including collecting broad clinical feedback and providing supply chain analytics, are especially important in rural and underserved areas. Individual practices and community hospitals do not have the resources, scale, and expertise to perform these services themselves. Further, many providers that use GPO contracts do not receive any administrative fee distribution, which means that the new burdensome reporting requirements would have an uneven impact across providers.

Re: Section 401: Requiring GPOs to annually report written agreements and disclosures to the HHS Secretary and OIG is burdensome and unnecessary due to the current level of GPO industry disclosure required by the Safe Harbor.

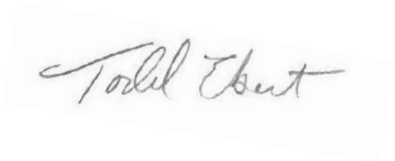
This provision does not solve the drug shortage crisis currently facing today's healthcare providers and the patients they treat. There is no rationale for requiring reporting to the government beyond the robust reporting already required by the GPO Safe Harbor. Pursuant to the GPO Safe Harbor, GPOs are currently required to disclose in writing all administrative fees earned on member purchases at least annually to their members and to the HHS Secretary upon request. The fact that HHS Secretary has never requested this information strongly suggests the current disclosure requirements are sufficient.

Further, the Committee's discussion draft does not specify how information relative to competition and confidential information will be handled, used, or protected. Requiring GPOs to share confidential information regarding their members and competitive arrangements creates contractual and legal concerns, including exposure to potential antitrust risks.

As part of our original response to the Joint Committee *Congressional Drug Shortages Request for Information* (submitted on July 7th, 2023), HSCA and its member GPOs provided a series of substantive recommendations to prevent and mitigate drug shortages, several of which build on existing congressional authorities. **We respectfully resubmit our short-term and long-term recommendations to help address drug shortages, included in Appendix A below**.

We appreciate the opportunity to provide the Committee with our insights. We look forward to working with the Committee as it revises and refines the *Stop Drug Shortages Act*, and continuing to be a resource to Congress and all stakeholders as we all work to improve healthcare in the U.S. 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,



Todd Ebert, R. Ph.
President & CEO
Healthcare Supply Chain Association (HSCA)

APPENDIX A

HSCA proposed policy solutions to prevent and mitigate drug shortages *(as originally included in the July 7, 2023, Response to the Joint Committee Congressional RFI on Drug Shortages)*

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 active pharmaceutical ingredient (API) sources, to support long-term access to generic medications. *(In response to question 2 of the Congressional RFI)*
Refine Authority Related to the Strategic National Stockpile (SNS)'s 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 vendor 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. (*In response to question 2 of the Congressional RFI)*
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. *(In response to question 4 of the Congressional RFI)*
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 quality products being made *and* sold in the U.S. (I*n response to question 6 of the Congressional RFI)*
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. *(In response to question 4 of the Congressional RFI)*

	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. *(In response to question 14 of the Congressional RFI)*
Mitigating Product Delays	Congress should encourage FDA to provide 503B compounding facilities with more flexibility to meet provider demand and loosen restrictions to allow 503b compounders to make certain high-risk products in anticipation of a potential shortage, rather than only in response to an existing shortage *(In response to question 14 of the Congressional RFI)*
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 suppliers and drug product manufacturers. *(In response to question 14 of the Congressional RFI)*