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before the
Subcommittee on Health, Committee on Energy and Commerce of the U.S. House of Representatives

"Legislative Proposals to Prevent and Respond to Generic Drug Shortages"

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Chairman Guthrie, Ranking Member Eshoo, and distinguished members of the Subcommittee:

Thank you for the opportunity to be here today to discuss the important role of traditional healthcare group purchasing organizations (GPOs) in preventing and mitigating drug shortages and the full Committee Chair's *Stop Drug Shortages* discussion draft. We appreciate your efforts to examine the pressing problem of drug shortages and we look forward to continuing to work with Congress and all stakeholders to preserve patient access to high-quality care.

I have 44 years of experience as a registered pharmacist, and I have seen firsthand the impact of drug shortages on patients and their families. As the former CEO of a GPO, and now as the head of the Healthcare Supply Chain Association, I have also witnessed the great work that healthcare GPOs do to prevent and mitigate drug shortages so that patients have timely and consistent access to the medications they need.

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. GPOs serve as the sourcing and contracting partners to hospitals, long-term care facilities, surgery centers, clinics, and other healthcare providers throughout 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] Traditional healthcare 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.

GPOs Take a Comprehensive Approach to Contracting that Accounts for Quality, Not Just Price

The GPO business model is voluntary, flexible, and clinically driven. Importantly, GPOs take a comprehensive approach to sourcing and contracting that not only accounts for the competitive price offered by suppliers, but also the quality, reliability, and stability of supply. GPOs recognize that market conditions change. When they do, GPOs work with suppliers to adjust contracts. GPOs also work to expand the overall number of suppliers, including encouraging new manufacturers to enter the market.

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, which generally includes multiple manufacturers. GPOs continue to work with suppliers to map out entire product supply chains and encourage manufacturers to identify alternative sources of active pharmaceutical ingredients (API).

[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.

HSCA member GPOs recognize that reliability and predictability are paramount for manufacturers. That is why contracts between GPOs and generic manufacturers serve to provide certainty and predictable, consistent demand that manufacturers need for capacity planning and production forecasts.

The GPO Market is Vigorously Competitive

GPOs create a vigorously competitive market for both GPOs and suppliers. 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, or purchase outside a GPO contract altogether. 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. A report by former Federal Trade Commission (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 vendor-administrative fee model is the most economically efficient model for the supply chain.[3]

Traditional Healthcare GPOs are Extremely Transparent

We appreciate the Subcommittee's interest in increasing transparency across the supply chain. The GPO Safe Harbor (42 C.F.R. § 1001.952(j)) – to which GPOs strictly adhere – includes robust transparency and reporting requirements by GPOs to their members, and, upon request, to the government.

HSCA's member GPOs provide detailed information to their member healthcare providers to ensure that any manufacturer rebates and any administrative fee shares are included in their annual Medicare cost reports.

Additionally, all non-governmental HSCA member GPOs also 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.

Traditional Healthcare GPOs are Distinct Entities from PBM Rebate Aggregators and Large Buying Groups

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,

[3] Leibowitz, Jon, et al., "Group Purchasing Organizations: How GPOs Reduce Healthcare Costs and Why Changing Their Funding Mechanism Would Raise Costs." Antitrust Source, June 2017.

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.

Drug Shortages Place an Enormous Strain on Hospitals and Patients, and are Antithetical to the GPO Model

As the Committee has noted, 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 UUDIS survey of manufacturers 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. Manufacturers who did respond cited supply/demand (19%), manufacturing (18%), business decisions (5%), regulatory issues (1%), and raw material issues (1%) as reasons behind shortages. It is worth noting, however, that manufacturers did not raise 'margin pressure' as a concern.

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 supplier business decisions to discontinue products.

Drug shortages are antithetical to the GPO model, as without sufficient products or suppliers, GPOs are unable to provide their services. 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 reliable access to the drugs, products, and services they need.

HSCA Supports the Committee's Recognition of the Role of 503B Compounders

HSCA and our member GPOs appreciate the full Committee Chair's recognition of the important role of 503b compounding facilities (*Section 503 of the discussion draft*), which are critical for acute and non-acute healthcare providers. We strongly support increasing flexibility for 503b compounders to mitigate and prevent drug shortages. In addition to expanding the role of 503b compounders, we recommend that Congress 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 potential shortages, rather than only in response to existing shortages.

HSCA Opposes Sections 305, 307, and 401, Which Will Exacerbate Access Challenges and Will Not Meaningfully Address the Current Drug Shortage Crisis

We are concerned about sections 305 and 401 in the *Stop Drug Shortages Act* discussion draft. These provisions will add to the significant administrative burden facing America's healthcare providers and

exacerbate access challenges to critical medicines, particularly among small and rural hospitals, without addressing the drug shortage crisis. In addition, we are concerned that section 307 will change the ASP definition and discourage suppliers from working with GPOs. We respectfully ask that the Committee remove these three provisions and have provided additional information below.

Re: Section 305: Requiring hospitals to report group purchasing remuneration under Medicare

HSCA joins the American Hospital Association, American Society of Health-System Pharmacists, Association of American Medical Colleges, and other healthcare stakeholders in opposing Section 305. 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)). Failure to comply with a Condition of Participation in Medicare can lead to expulsion from the Medicare and Medicaid programs. Raising the existing reporting requirement to a Condition of Participation will subject hospitals to a new level of sanctions, contradicting the Centers for Medicare and Medicaid Services (CMS) 2019 "Patients over Paperwork" initiative, as implemented under the Omnibus Burden Reductions final rule.[4]

American hospitals are already operating at razor-thin margins and face an increasing number of closures, particularly among small and rural hospitals. Creating additional burdensome requirements will unnecessarily strain workforce resources when they can least afford it. We are concerned that making remuneration information broadly available will also give rise to privacy and competition concerns.

The term "remuneration" is also vague and broad. We are concerned it would likely be inconsistently applied and would lead to extremely burdensome requirements. We strongly recommend that Congress enforce the current requirements pertaining to the reporting of discounts on cost reports instead of implementing new and additional requirements, as hospitals should focus on patients, not paperwork.

Re: Section 307: Requiring clarification of Medicare average sales price payment methodology to provide a statutory definition for bona fide service fees

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 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). In other words, this provision would cut hospital reimbursements for drugs as a penalty for

[4] "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.

using a GPO. 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* discussion draft 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 not to use a GPO, thus decreasing supply chain efficiencies, creating further fragmentation in the healthcare supply chain.

Health systems and independent physician offices depend on GPOs for much more than just their ability to collectively aggregate purchasing power. Other services GPOs provide include collecting 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 these services themselves. Further, to the extent that not all providers using GPO contracts receive any administrative fee distribution, 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

As mentioned above, we recognize and support the Subcommittee's interest in increasing transparency across the healthcare supply chain. However, this provision does not solve the drug shortage crisis currently facing today's healthcare providers and the patients they treat. We do not see any rationale for requiring reporting 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.

We are further concerned about this provision because it does not specify how information relative to competition and confidential information will be handled, used, or protected. Requiring GPOs to share confidential information regarding our members and competitive agreements creates contractual and legal concerns, including exposure to potential antitrust risks. Another possible unintended consequence of this provision is the hundreds of thousands of pages of documentation it would generate, again, with no clear rationale as to how sifting through these disclosures and contracts would address drug shortages.

HSCA Offers Substantive Recommendations to Help Prevent and Mitigate Drug Shortages

We understand that solving the drug shortage crisis is a complex task. On July 7th, 2023, HSCA submitted its response to the Joint Committee *Congressional Drug Shortages Request for Information*. In our response, we provided the Joint Committee with a series of substantive recommendations that will help prevent and mitigate drug shortages, several of which build on existing congressional authorities, including:

Investing in Quality and Building Secondary Supply Lines
HSCA recommends incentivizing not just production, but investment in quality and capacity, including the addition of secondary supply lines and having alternate, or backup API sources to support long-term access to generic medications.

Refining 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 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 products should be released.

Maintaining and/or Requiring Buffer Inventory
To increase critical access to drugs, HSCA and our member GPOs recommend 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.

Creating Incentives to Increase Domestic Manufacturing
HSCA recommends that if Congress elects to create incentives related to increasing 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.

Increasing Transparency
As mentioned above, HSCA champions transparency across the supply chain. HSCA and our member GPOs recommend 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. Additionally, we recommend that Congress fully fund FDA's quality management maturity (QMM) program and require manufacturer participation and implementation as soon as possible. Furthermore, HSCA recommends that FDA share its QMM ratings with appropriate supply chain stakeholders, including GPOs, to best inform purchasing decisions.

Increasing Facility Inspections

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

<u>Conclusion</u>

We appreciate the opportunity to provide our comments to the Subcommittee 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 to continue improving the healthcare system. Thank you.

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