

March 29, 2023

The Honorable Bernie Sanders Chair, Committee on Health, Education, Labor and Pensions United States Senate Washington, DC 20510

The Honorable Robert P. Casey, Jr. Member, Committee on Health, Education, Labor and Pensions United States Senate Washington, DC 20510 The Honorable Bill Cassidy, M.D. Ranking Member, Committee on Health, Education, Labor and Pensions United States Senate Washington, DC 20510

The Honorable Mitt Romney Member, Committee on Health, Education, Labor and Pensions United States Senate Washington, DC 20510

Dear Chair Sanders, Ranking Member Cassidy, Senator Casey, and Senator Romney,

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 the Senate Health, Education, Labor, and Pensions (HELP) Committee with our recommendations on the reauthorization of the Pandemic and All-Hazards Preparedness (PAHPA) Act. HSCA applauds your leadership and bipartisan efforts to increase U.S. pandemic and public health emergency preparedness.

Healthcare GPOs are the sourcing and purchasing 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. GPOs work with providers to negotiate competitive prices and support a safe and reliable supply of products. GPOs lower costs for patients, providers, payers, Medicare and Medicaid, and taxpayers. A 2018 <u>analysis</u> found that GPOs save the U.S. healthcare system \$34.1 billion annually, up to \$456.6 billion over ten years, and up to \$116.3 billion in Medicare savings and \$90.2 billion in Medicaid savings over the same period.

GPOs allow small and rural healthcare providers – who often lack the purchasing power to access competitive pricing for essential supplies – to take advantage of the same efficiencies and discounts as larger providers. The value and services that GPOs provide allow healthcare providers and physicians to focus on their core mission: providing first-class patient care.

Pandemics and other public health emergencies place enormous stress on the entire healthcare system. Healthcare GPOs have played a critical role in supporting COVID-19 response efforts, working closely with all stakeholders, including federal, state, and local health and emergency management agencies to ensure that America's providers have the supplies they need to safeguard patient care. GPOs have taken a number of innovative steps to combat the COVID-19 pandemic, including adding new and nontraditional suppliers and manufacturers to contracts to shore up domestic manufacturing; proactively communicating patient volumes and product demand surges to help expand manufacturing capacity for PPE and other vital supplies; harnessing data and cutting edge technology to provide supply chain insights and improve care; and protecting healthcare providers from counterfeit or inferior products.

<u>Given the unique line of sight of GPOs over the entire healthcare supply chain, HSCA and its member</u> <u>GPOs respectfully recommend the following:</u>

Public Health Emergency Coordination and Policy

§2. The authorities, duties, and functions of the Assistant Secretary for Preparedness and Response (ASPR)

HSCA recommends that Congress provide the Administration for Strategic Preparedness and Response (ASPR) and the Food and Drug Administration (FDA) with the joint authority to require that manufacturers and providers of raw materials and active pharmaceutical ingredients (API) disclose information regarding quantity, location, and predictable shortages of critical supplies. This information is essential to strengthening the healthcare supply chain and particularly important for maintaining adequate inventory of pharmaceuticals, medical devices, and personal protective equipment (PPE). HSCA also recommends that this information be made available to ASPR and FDA and that the agencies and Congress develop a process, consistent with national security considerations, to make some or all of the quantity, location, and supply information available to GPOs and other supply chain entities.

The Food and Drug Administration Safety and Innovation Act (FDASIA), enacted in 2012, required manufacturers to notify FDA of changes in the production of certain finished drugs and biological products that may assist the agency's efforts to prevent and mitigate shortages. The Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 expanded the FDA notification requirement to include interruptions in production of active pharmaceutical ingredients. While tracking APIs is an important step, HSCA recommends that Congress provide FDA and ASPR with the joint authority to require that manufacturers of essential healthcare products and product components also report potential shortages. The FDA received new authority relating to healthcare device shortages in the CARES Act and has used the information collected under these new authorities to help <u>mitigate</u> 350 of 455 potential reported device shortages.

Medical Countermeasures Development and Deployment

§1. The Strategic National Stockpile (SNS)

HSCA recommends that Congress require the SNS to include private-sector entities in its supply chain review processes through Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) to ensure that SNS products are up-to-date, current with medical best practices, and inclusive of special populations, such as pediatrics, emergency medical services (EMS), law enforcement, jails, and prisons. Private-sector entities offer valuable perspectives on SNS maintenance, procurement, and distribution plans. Maintaining a safe supply of medications, medical countermeasures, and products within their expiration dates and rotating stock where necessary is critical to overall emergency preparedness.

Healthcare GPOs are well positioned to help SNS and its governing agencies better understand market dynamics and assist with the development of processes to sell and distribute excess products without disrupting existing supply chains. A sudden influx of low-cost inventory from SNS into the market could remove critical predictability of demand from current suppliers, which, in turn, could lead to a decrease in production. As products approach their expiration dates and are eligible for sale, private-sector entities can help SNS consider the best processes for distribution, critical elements of the financial transactions, and chain-of-custody issues, among other considerations.

SNS helps state and local public health agencies manage large quantities of medical countermeasures through the Inventory Management and Tracking System (IMATS), which allows responders to track inventory down to local levels, monitor reorder thresholds, and support warehouse operations. HSCA recommends data gathered by SNS, either through IMATS or other processes, be made available to the private sector consistent with the requirements of management of Confidential Business Information (CBI) and appropriate national security considerations.

§4. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and related strategy, implementation plan, and budget plan

HSCA recommends that Congress direct the SNS to involve GPOs and other supply chain stakeholders in the preservation and maintenance of the Strategic National Stockpile (SNS) through the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). PHEMCE is led by ASPR and includes three primary HHS internal partners, the Centers for Disease Control and Prevention (CDC), the FDA and the National Institutes of Health (NIH), as well as several interagency partners: the Department of Defense (DoD), the U.S. Department of Veterans Affairs (VA), the Department of Homeland Security (DHS) and the U.S. Department of Agriculture (USDA). HSCA and its member GPOs work with many of these federal agencies on key supply chain issues. For example, HSCA offered <u>comments</u> to the FDA on the "Risk Management Plans to Mitigate the Potential for Drug Shortages" draft guidance in 2022 and has met with representatives from ASPR several times over the past year to discuss how GPOs and the private sector can support the Strategic National Stockpile (SNS). HSCA and its member GPOs hope to continue collaborating with partners across the public sector to bolster resiliency and transparency across the supply chain.

Partnerships

HSCA recommends that Congress allow for information about pandemics and other public health emergencies, including potential shortages, to be safely shared with private-sector entities. The GPO industry has provided critical support to healthcare providers during emergencies like Hurricane Harvey, the California wildfires, and outbreaks of infectious diseases such as Ebola and COVID-19. Greater transparency and data-sharing between the public and private sector will allow all stakeholders to take a more proactive approach. GPOs support providers and patients nationwide by ensuring a consistent supply of safe, effective medications and healthcare products. Private-sector entities, including GPOs, are well-equipped to help providers navigate public health emergencies and work with the public sector to prevent disruptions to patient care.

We appreciate the opportunity to provide the Committee with our perspective and we look forward to continuing to serve as a resource to your offices, other Members of Congress, and all stakeholders to help ensure U.S. pandemic and public health emergency preparedness. 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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Todd Ebert, R. Ph. President & CEO Healthcare Supply Chain Association (HSCA)