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**STATEMENT
of the
Federation of American Hospitals
to the
United States Senate Committee on Finance**

**Re: “DRAFT Medicare Drug Shortage Prevention and Mitigation Program”
April 1, 2024**

The Federation of American Hospitals (FAH) submits the following feedback to the Senate Committee on Finance draft Medicare drug shortage proposal entitled “Medicare Drug Shortage Prevention and Mitigation Program.” We commend the Committee’s leadership in addressing the challenges associated with drug shortages and enhancing access to vital generic drugs in the United States.

As the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States, FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. We appreciate this opportunity to provide input on the Committee’s proposed Medicare Drug Shortage Prevention and Mitigation Program.

Drug shortages – particularly for commonly used generic drugs in hospitals – can impede patient care and force pharmacy and clinical staff to use less optimal alternatives. Hospitals and health systems, along with their group purchasing organizations (GPOs), employ numerous strategies to prevent and manage care through drug shortages. The Food and Drug Administration’s (FDA) Drug Shortages Task Force cited three main reasons for drug shortages:

- Lack of incentives for manufacturers to produce less profitable drugs diminishes their motivation to maintain or enter markets for older prescription drugs.
- The market inadequately rewards manufacturers for mature quality systems, hindering investments in manufacturing quality and redundancy.
- Logistical and regulatory challenges complicate efforts to recover from disruptions in the supply chain, which has become increasingly complex and fragmented.¹

The FAH is concerned that the draft Medicare Drug Shortage Prevention and Mitigation Program does not address the leading causes of drug shortages. We believe that incentivizing more than 5,000 hospitals to stockpile drugs beyond patient needs may lead to inequitable distribution of drugs across the health system. Additionally, we are concerned that the program, as outlined, will create significant burdens for hospitals

¹ US Food and Drug Administration, 2019, Drug Shortages: Root Causes and Potential Solutions.
<https://www.fda.gov/media/132058/download?attachment>

seeking to maintain and account for “buffer stock” as the challenge of working with a distributor to maintain extra stock of more than 80 different drugs, ensure that those drugs are used before their expiration, and account for systems and storage costs would create significant challenges and cost. To achieve the Committee’s goal of preventing and mitigating drug shortages, the FAH offers the following recommendations:

1. **Align Incentives Upstream:** Redirect incentives further upstream towards manufacturers and wholesalers to encourage them to maintain adequate drug inventories and enhance their quality management processes. This could include incentivizing manufacturers to maintain stockpiles, thus ensuring a consistent supply of active pharmaceutical ingredients (API), developing measures and ratings on the quality management processes of manufacturers, and making the ratings publicly available.
2. **Government Oversight on API Supply:** Implement measures to ensure a stable supply of API, domestically and overseas, particularly for mission-critical drugs. This may involve incentivizing manufacturers to maintain reserves and ensuring transparency around potential shortages. Requiring manufacturers to notify the FDA of unusual spikes in demand for essential drugs will allow the agency to take steps to mitigate or prevent potential shortages.
3. **Global Perspective:** Acknowledge the global nature of the pharmaceutical market and consider strategies such as importing drugs from other countries to mitigate shortages. Additionally, engage in proactive measures at the international level to address supply chain challenges, such as requiring manufacturers to disclose to the FDA the locations where their products are manufactured. This could help illuminate drug shortage vulnerabilities, allowing the FDA time to develop strategies to strengthen the supply chain.
4. **FDA Oversight and Engagement:** Advocate for a balanced approach from the FDA in regulating drug manufacturing facilities. Ensure that FDA actions, such as shutdowns or inspections, are appropriately timed and considerate of their impact on drug supply. Encourage more engagement and collaboration between stakeholders to address regulatory issues effectively.

By adopting these recommendations, the Committee can develop a more comprehensive and effective approach to preventing and managing drug shortages, emphasizing upstream solutions, and collaboration across the healthcare supply chain.

Finally, The FAH provides the following perspective on the critical role that GPOs play every day to promote a steady, affordable supply of vital drugs and other supplies for our healthcare delivery system and the patients, caregivers, and communities they serve.

GPOs play a pivotal role in the United States’ healthcare ecosystem, particularly in facilitating the procurement of essential medications for hospitals and health care providers. Unfortunately, GPOs are often erroneously implicated in contributing to drug shortages. Modern day drug shortages are fundamentally a problem of *supply-side* dynamics, when a manufacturer is unable to deliver enough products to satisfy predictable, recurring demand²—not by demand-side purchasers such as GPOs, which maintain efficiency, consistency, and significantly lower costs in an uncertain market. Contrary to misconceptions, GPOs actively work to stabilize the supply chain by advocating for policies that support uninterrupted access to medications. In the pharmaceutical supply chain, which comprises suppliers, manufacturers, distributors,

² See, e.g., Berkeley Lovelace Jr., How One U.S. Drugmaker Contributed to the Escalating Drug Shortage Crisis, NBC NEWS, July 16, 2023

and GPOs, any disruption can significantly hinder providers' ability to obtain pharmaceutical supplies and treat patients.

The primary function of GPOs is to streamline procurement processes for healthcare providers, including hospitals and clinics, by negotiating contracts with pharmaceutical manufacturers and distributors. GPOs negotiate prices using a manufacturer-bidding model, where GPOs solicit quotes from manufacturers. Importantly, it is the *manufacturer* that proposes the price it would accept in exchange for reliable demand for a period of years. In the experience of FAH's members, drug shortages often happen when a manufacturer—having won a competitive bid with a low price—may later determine that the price it bid was *too* low. Thus, the manufacturer may no longer find it financially viable to continue to invest in and produce the product.

GPOs diligently monitor manufacturers to ensure contract compliance and performance to uphold their commitment to member facilities and patients. Often, GPOs will include provisions for manufacturers to maintain adequate inventory levels, high quality standards, and ensure timely delivery to prevent shortages. By fostering strong relationships with suppliers and implementing proactive inventory management strategies, GPOs contribute to supply chain resilience and continuity of care.

We thank you for your focus on addressing drug shortages and look forward to working with the Committee on these critical issues.