

HDA Guiding Principles for Drug Shortages






(Updated 2/23/24)

Introduction

Healthcare distributors recognize the challenges drug shortages pose to the healthcare system and patients. Distributors play a key role in [addressing drug shortages](#), as their position in the supply chain allows them to have some insights into upstream availability and downstream provider needs. These capabilities enable distributors to respond to different types of drug shortages with tools to ensure equitable access to available product.¹

The distribution industry has developed these guiding principles on drug shortages to inform how distributors approach policies and leading practices on the issue. The topic of drug shortages is highly nuanced and requires an appreciation of the strengths of the supply chain, as well as capability required during times of surge. Any policy solution to address drug shortages should leverage these strengths, with an overall goal of bolstering supply chain resilience.

Our guiding principles are as follows:

-  **1 Each drug shortage has a unique root cause and driver.** Policies to address them should manage this nuance, as “blanket” policies will fall short.
-  **2 Different tools can help or hinder the response to drug shortages.** Policies should enable and retain the tools used to mitigate and manage shortages, while also preventing behaviors that make addressing drug shortages more challenging.
-  **3 Downward pressure pushes stakeholders to lower drug prices in an unsustainable way. Economic policies must acknowledge the complex environment stakeholders operate in.** Policies to address drug shortages must acknowledge the lower costs stakeholders are pressured to create for the benefit of patients.
-  **4 Drug shortages related to geographic market concentration can be a matter of national security.** A lack of geographic diversity for medicines presents a strategic risk to national security.
-  **5 Partnerships between industry and government should be nimble.** Flexible solutions are applicable to different types of shortages.

Guiding Principles

Each Drug Shortage Has a Unique Root Cause and Driver



Drug shortages require specific mitigation strategy and response due to various causes and underlying factors. For this reason, it is difficult to “solve for shortages” with a blanket approach. Further, drug shortages may also differ by impact and duration, which can change how those should be addressed.

Perspective: Whether a drug shortage is [supply-driven](#) or [demand-driven](#), all drug shortages result from the available supply not meeting the current demand.² Drug shortages range in root cause and severity, making it a complex and nuanced issue. Because of the diverse root causes of drug shortages, policy solutions to prevent drug shortages must be nimble and rooted in sustainable market-based solutions. Supply-driven shortages most often affect generic drugs because generic drugs are more vulnerable to manufacturing challenges and raw material shortages.³ Demand-driven shortages impact both brand and generic drugs based on medical surge or harmful behaviors such as overprescribing and hoarding.⁴ Policy solutions for drug shortages should not be looked at in a one-size-fits-all lens.

Different Tools Can Help or Hinder Managing Drug Shortages

Strategies to manage drug shortages should be maintained to manage available resources efficiently and equitably. All stakeholders must uphold practices that create equitable outcomes for providers and patients, especially stakeholders responsible for facility purchasing.

Perspective: Distributors [mitigate and manage drug shortages](#) as a core part of their business. Distributor capabilities include intelligence gathering, communication with manufacturers and strategic inventory management to track available products or potential disruptions. Distributors lessen the effects of an ongoing drug shortage by using strategies such as fair-share allocation programs, supporting stockpile expansion, leveraging national distribution networks, and using just-in-time inventory management systems to manage drug shortages.⁵

In trying to manage a drug shortage, provider needs in coordination with facilities (such as clinics, rural access hospitals and others) may unintentionally create inequitable outcomes through behaviors such as overbuying or hoarding medicines. Hoarding often occurs in response to a rumor of a manufacturing issue, such as an FDA Form 483⁶ or a disruption. Hoarding creates challenges for facilities with less buying power, as those facilities are not able to purchase at the same level and will not be able to access product. This dynamic explains the need for distributor fair-share allocation programs, as hoarding can create artificial drug shortages. Fair-share allocation programs limit the amount of product that a single customer can purchase. This ensures that products are equitably distributed, so supply is available to as many sites of care as possible.



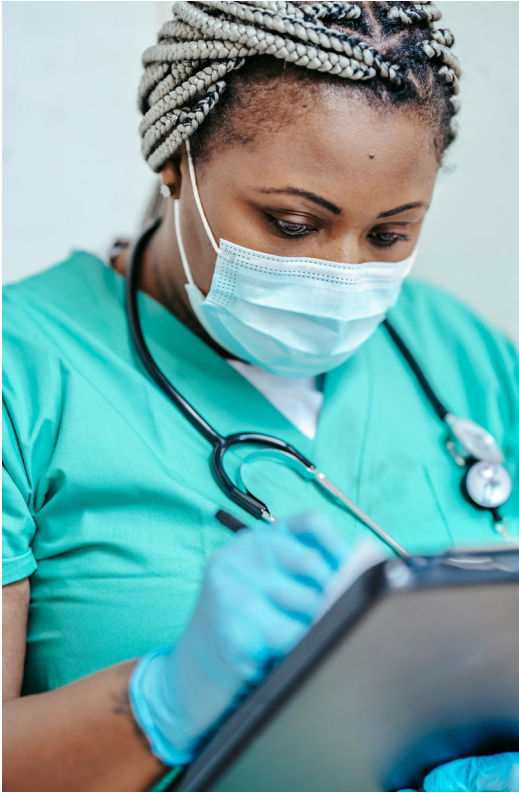
Economic Dynamics Must Be Considered as Reimbursement Policies Shift

Additional downward pressure on specific components of the supply chain can strain stakeholders with limited resources — such as generic manufacturers ([18.2 percent net profit](#)), distributors ([0.4 percent net profit after taxes](#)) and pharmacies ([4.0 percent net profit](#)). In an already complex pharmaceutical supply chain, stakeholders are working to identify and resolve challenges that lead to shortages. Policies should be carefully considered so they do not increase economic pressures.

Perspective: Drug shortages affect pharmaceutical supply chain stakeholders differently. On the upstream side (i.e., sourcing and manufacturers processes), generic manufacturers are penalized through inflation penalties. On the downstream side (i.e., consumers and sites of care), pharmacies are operating with lower reimbursement. The pressure to lower drug prices, especially generic drug prices, has resulted in challenging economic dynamics for upstream and downstream stakeholders.⁷ Pharmacies and other sites of care are continuously pressured to pay the lowest price possible for medicines. Pharmacies are reimbursed at low rates,⁸ which lowers pharmacy profitability. This drives pharmacies to seek lower-priced products (especially generic drugs) and pressure distributors to buy at the lowest price possible. Distributors must source products at the price the customer is willing to pay, while also finding a sustainable supply of products. This dynamic then results in the manufacturer having to operate on a lower operating margin that may not be sustainable for production. Financial pressures from reimbursement dynamics create further pressure upstream for manufacturers.

Every upstream and downstream stakeholder is working to drive down the cost of medicines. This results in every stakeholder operating in a constrained environment, with limited revenue to make sustainable investments that ensure a consistent and reliable supply of medicines, especially generic medicines. Increasing reimbursement for specific medicines in or near shortage can alleviate the economic dynamics both upstream and downstream stakeholders' experience. Solutions to adjust reimbursement policies include alleviating rebate obligations for manufacturers of generic drugs prone to shortage and specific medical products deemed vulnerable to shortage or disruption. Alleviating rebate obligations for specific generic drugs may improve product availability, profitability and market stability for both upstream and downstream stakeholders. Other solutions include adjusting reimbursement policies to increase provider reimbursement for generic drugs to alleviate downward pressure on healthcare facilities. In addition, we encourage reviewing the outcome of Hatch-Waxman and the Generic Drug User Fee Amendments (GDUFA) to determine if these policies are sustainable in today's generic drug marketplace. We also recommend that the Centers for Medicare and Medicaid Services (CMS) and the U.S. Food and Drug Administration (FDA) coordinate the review of suppliers for a given generic drugs to determine the sustainability of the market.

Managing Supply Vulnerabilities Can Also Be a Matter of National Security



A lack of geographic diversity for medicines poses a strategic risk to national security. Increasing geographic diversity in the pharmaceutical supply through domestic manufacturing may mitigate drug shortages and increase national security.

Perspective: The availability of medicines, especially medical countermeasures, plays a key role in response to a disaster or disease outbreak. Additionally, the concentration of medical manufacturing in one country or geographic region can pose a threat in the case of geopolitical conflict. These factors are different variables than others on drug shortages — and do require different solutions and investment to address. As most solutions for drug shortages should be market-based, strategies to prepare for and respond to an event may differ. National security solutions such as strategic stockpiling and domestic manufacturing (or onshoring at-risk products) require an investment from federal government to initiate and maintain.

Solutions to increase domestic manufacturing of active pharmaceutical ingredients/key source materials and finished dose products couples drug shortages mitigation with national security interests. Domestic manufacturing of select products does not automatically resolve drug shortages or guarantee resilient infrastructure. However, domestic manufacturing could

benefit U.S. national security interests because it increases geographic diversity for manufacturing. Increasing product geographic diversity increases supply chain resilience as the supply chain is less vulnerable to disruptions and geopolitical events. We support domestic manufacturing solutions that include significant nuance in alignment with national security interests.

Partnership between industry and government should be nimble

The partnership between the federal government and industry should be mutually beneficial.

Perspective: The federal government should utilize existing [public-private partnerships](#) to address drug shortages. Government should partner with industry to supplement industry's expertise and capabilities to mitigate and manage drug shortages. The insights and solutions that result from partnerships between industry and government should be adaptable to address drug shortages with different root causes, duration and levels of severity.

For additional HDA materials and information on drug shortages, visit:
<https://www.hda.org/drug-shortages/>.

Endnotes

- 1 Healthcare Distribution Alliance. "Understanding Drug Shortages: An Overview and Recommendations." 2023. <https://www.hda.org/getmedia/dd890154-f8fa-48c0-9c8f-ce75b81cfd82/Understanding-Drug-Shortages.pdf>.
- 2 Healthcare Distribution Alliance. "Mitigating and Managing Drug Shortages: The Role of Healthcare Distributors." 2023. <https://www.hda.org/getmedia/984131d4-5163-411a-b74b-f3467113146b/Mitigating-and-Managing-Drug-Shortages.pdf>.
- 3 IQVIA Institute For Human Data Science. "Drug Shortages in the U.S. 2023: A Closer Look at Volume and Price Dynamics." 2023. <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/drug-shortages-in-the-us-2023/drug-shortages-in-the-us-2023.pdf>.
- 4 Healthcare Distribution Alliance. "Understanding Demand-Driven Drug Shortages." 2023. <https://www.hda.org/getmedia/f2d7f204-ea19-434b-a8a4-c0bc5610f08f/HDA-Understanding-Demand-Driven-Drug-Shortages-Factsheet.pdf>.
- 5 Healthcare Distribution Alliance. "Drug and Medical Product Availability: Distributors Promote a Resilient Supply Chain." 2023. <https://www.hda.org/getmedia/45f48c39-69e6-4ff8-8919-af1c4cfb7432/Drug-and-Medical-Supply-Shortages.pdf>.
- 6 An FDA Form 483 is issued at the conclusion of inspection of where an FDA investigator has observed conditions that may constitute violations of the Food Drug and Cosmetic Act.
- 7 Healthcare Distribution Alliance. "HDA RFI Submission – Drug Shortages." 2023. <https://www.hda.org/getmedia/cc3658b0-cebe-47cd-a944-0af2504ece9a/HDA-RFI-Submission-Drug-Shortages.pdf>.
- 8 Gebelhoff, Robert. "Opinion: The U.S. pharmacy industry is crumbling. Here's how to fix it" *The Washington Post*. November 28, 2023. <https://www.washingtonpost.com/opinions/2023/11/27/pharmacies-closures-drugs-medicare-medicare/>.

About the Healthcare Distribution Alliance

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.