

The Federal Government Should Lead on Drug Shortages Solutions

[Ongoing drug shortages](#) are impacting patient access to crucial medicines, drawing concern from policymakers at all levels of government. However, drug shortages are highly complex and nuanced, with varying root causes — making them difficult to address through a piecemeal, state-by-state approach.

The global nature of the pharmaceutical supply chain requires a cohesive national policy approach to effectively respond to drug shortages. **States seeking to address drug shortages should coordinate with the federal government to ensure state proposals do not impede ongoing federal efforts and avoid the creation of a patchwork of state laws.**

Ultimately, any policy responding to drug shortages should leverage the strengths of the pharmaceutical supply chain, with an overall goal of bolstering supply chain resilience.



Drug shortages occur due to a variety of factors and can often be categorized as either a [supply-driven](#) or demand-driven shortage. Supply-driven drug shortages often result from upstream disruptions, such as key source material (KSM) or active pharmaceutical ingredient (API) sourcing disruptions; disease outbreaks; or manufacturing and quality issues. [Demand-driven](#) drug shortages often result from medical surge.

Federal Activities on Drug Shortages

- Due to the global nature of the pharmaceutical supply chain, Congress and federal agencies have the most substantial legislative and regulatory tools to address drug shortages. Current actions and policy proposals to respond to drug shortages include strategies to create more capacity in manufacturing or improve economic dynamics in the generics market. For example:
- The Food and Drug Administration (FDA) maintains a drug shortage list and works with manufacturers to prevent and manage ongoing shortages.
- FDA's drug shortage team works closely with industry stakeholders to prevent new shortages and resolve existing shortages.
- Due to the lack of geographic diversity for active pharmaceutical ingredients (API), the federal government has invested in domestic API manufacturing. Notably, the Administration for Strategic Preparedness and Response invested \$500 million in domestic API manufacturing.

- The Centers for Medicare and Medicaid (CMS) finalized a [new rule](#) establishing a separate payment under Medicare for small, independent hospitals to create a six-month buffer stock of specific [medicines](#). Congress and HHS are considering similar proposals.
 - Buffer stock strategies can be challenging for states to implement because of the costs associated with establishing and managing buffer stock, rotating inventory and refreshing the stock based on evolving needs.
- Federal policymakers launched a [bipartisan caucus](#) and introduced legislation [boosting](#) domestic manufacturing through [reshoring incentives](#).
 - The federal government is best positioned to invest in domestic manufacturing for medical products because its branches can provide financial incentives and guarantee purchasing.
- Federal policymakers are seeking to [stabilize the generics market](#) by adjusting Medicare provider reimbursement and alleviating Medicaid economic challenges for generic drug manufacturers.
 - Reimbursement and economic policy changes are needed at the federal level to impact the U.S. generics market consistently.



State policymakers should consider how policy proposals could unintentionally strain a [complex](#) pharmaceutical supply chain — and potentially lead to further drug shortages. HDA and our distributor members encourage state lawmakers to ensure their policy efforts are coordinated with the federal government’s actions to address drug shortages.

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.