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Addressing generic drug shortages: Contributing factors and public policy recommendations

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Introduction

With over 100 years of excellence in pharmaceutical supply chain management, Cencora is renowned for its commitment to patient care, expertise in pharmaceutical distribution, and deep understanding of market access dynamics. Our insights into the complex issues contributing to global drug shortages and their solutions are informed by our position as one of the world's largest pharmaceutical wholesale distributors of prescription drugs. Cencora seeks to partner with the U.S. Congress and the Administration to tackle these challenges, enhancing care delivery, patient access, and outcomes in the United States while harmonizing global solutions.

Drug shortages, particularly of generic drugs—including both sterile injectables and oral solids—negatively impact millions of patients and healthcare providers across the U.S. These shortages are complex and require coordinated public-private efforts to identify contributing factors and develop effective policy solutions. As a vital member of the pharmaceutical supply chain, Cencora aims to collaborate with federal and state policymakers, regulators, and the Administration to enhance care delivery, improve reimbursement processes, and increase supply chain transparency and resilience.

This white paper outlines recommended approaches to combat generic drug shortages and improve patient access and outcomes, while improving U.S. national security. It is structured to provide an executive summary, background on the issue of generic drug shortages, a snapshot of the current state of the generic drug shortages, key pillars and players involved in mitigating risks, and short-, mid-, and long-term policy recommendations to serve as solutions for providers, patients, and supply chain stakeholders.

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Executive summary

Contributing factors of generic drug shortages

Cencora's recommended public policy solutions address the contributing factors of generic drug shortages and aim to mitigate and prevent the ongoing issue. These recommendations are categorized into three main themes: sustainable and reliable manufacturing, supply assurance programs, and tax incentives. These policy initiatives are outlined in greater detail later in this paper.

Generic drug shortages contributing factors

- Challenges to diversification and sourcing of active pharmaceutical ingredients (API)
- Disruptions impacting the generic supply chain
- Uncertainty of the generic drug manufacturing market
- Limited visibility into global mapping of generic medications
- Unsustainable generic drug pricing and reimbursement

Overview of Cencora's public policy recommendations

Short-term solutions

Sustainable and reliable generic drug manufacturing

Shortage-Prone Generics (SPG) Program

This original program establishes a foundation for mitigating generic drug shortages by identifying and listing "shortage-prone generic drugs" (SPGs). Manufacturers of SPGs or SPG inputs that meet specific criteria would qualify for tax credits. Additionally, providers who purchase SPGs from these manufacturers and meet certain conditions would receive a separately payable Medicare reimbursement based on the SPG's non-aggregated Average Sales Price (ASP) plus an add-on percentage.

To effectively address the challenges faced by both provider communities and manufacturers, the SPG program must include the following components:

- **Manufacturer participant incentive:** Establish a formulary and quality bonus program for domestic manufacturers of generics, biosimilars, and "critical" drugs to stabilize drug pricing.
- **Medicaid inflation rebates:** For generic drugs that are in or at risk of shortage, the U.S. Congress should suspend Medicaid inflation rebates that discourage stable price increases. This action would decrease the rate at which generic manufacturers exit the market, thereby enhancing competition and expanding provider choices.
- **Provider reimbursement incentive:** Establish a sustainable, minimum reimbursement for providers that purchase generic drugs from SPG manufacturers and reduce inflation rebate amounts for certain shortage drugs subject to rebate waivers under the Medicare program.

Mid-term solutions

Increasing stability of supply: Supply assurance programs

Essential Medicines Reserve (EMR)

To stabilize the market, investments in a U.S. Health and Human Services (HHS) pilot program for an essential medicines reserve, and/or a pilot program to establish an essential medicines strategic stockpile (EMSS) inventory, as outlined in the Essential Medicines Strategic Stockpile Act (EMSSA) (H.R. 405 in the 118th Congress), are crucial. These initiatives will create assurances to address manufacturing redundancies and bolster reserves for provider and patient demand.

- Additionally, Cencora recommends that U.S. states collaborate with pharmaceutical logistics experts to enhance demand stability through supply assurance programs. These initiatives would incentivize generic manufacturers and help maintain supply during drug shortages and emergencies at the state level.

Medicare Conditions of Participation

New Medicare conditions of participation (CoPs) should require every provider and hospital, especially those eligible under the CMS Inpatient Prospective Payment System (IPPS) rule, to have a generic drug shortage prevention and inventory plan annually reviewed and approved by the CEO of U.S. hospitals and health systems.

Long-term solutions

Improving the resilience of the domestic supply chain and diversification of sources: Tax incentives

Tax incentives related to reserves and manufacturing capacity

Provide a tax incentive for domestic generic drug manufacturers to hold reserves and increase manufacturing capacity for drugs likely to experience shortages.

Tax incentives related to increased U.S. production

Provide tax incentives for:

- Drug manufacturers to produce generic drugs in economic opportunity zones, which have historically served as an incentive for development in rural areas of the U.S. and its territories, including the Commonwealth of Puerto Rico
- Generic drug manufacturers to increase U.S. production through a modified version of the Creating Helpful Incentives to Produce Semiconductors (CHIPS) and Science Act of 2022
- Generic drug manufacturers to seek Abbreviated New Drug Applications (ANDAs) approval to increase U.S. production

As policymakers aim to address drug shortages and strengthen the pharmaceutical supply chain, Cencora supports effective policy solutions informed by our unique supply chain perspective. We are committed to ongoing engagement with key stakeholders and the government to tackle the critical issue of generic drug shortages affecting patient access and care both in the U.S. and globally.

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U.S. generic drug shortages background

The U.S. is experiencing drug shortages of more than 130 drugs, including critical cancer drugs.[1] A 2023 survey from the Society of Gynecologic Oncology indicated that doctors in 35 states reported limited to no supply of key chemotherapy drugs at major facilities like large cancer centers and teaching hospitals.[2]

While individual drugs go into and come out of shortage status, persistent and recurring drug shortages, **specifically of generic drugs**, have been an issue in the U.S. and the global supply chain for many years. According to the U.S. Food and Drug Administration (FDA), generic drugs are "bioequivalent substitutes" for brand-name medications, providing the same dosage form, safety, strength, administration route, quality, and intended use.[3] Notably, 90% of patients in the U.S. rely on generic drugs.[4]

The reasons behind drug shortages are as complicated and multi-faceted as the drug supply chain itself. To effectively address the underlying drivers of generic drug shortages, policymakers must adopt a comprehensive approach that addresses Challenges to diversification and sourcing of active pharmaceutical ingredients (API), disruptions impacting the generic supply chain, uncertainty of the generic drug manufacturing market, limited visibility into global mapping of generic medications, and unsustainable generic drug pricing and reimbursement. In this paper, we outline the key issues that policymakers need to address, along with corresponding policy solutions, categorized into three main themes: **sustainable and reliable manufacturing, supply assurance programs, and tax incentives.**

[1] Drug Shortages Near an All-Time High, Leading to Rationing - The New York Times (nytimes.com)
[2] Drug Shortages Near an All-Time High, Leading to Rationing - The New York Times (nytimes.com)
[3] https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers
[4] IMS Institute for Healthcare Informatics. The use of medicines in the United States: review of 2011. Danbury (CT): IMS Institute for Healthcare Informatics; 2011

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The cost of drug shortages

Drug shortages have detrimental ramifications on patients' access to necessary medications. As reported by the American Society of Health-System Pharmacists (ASHP), the number of ongoing and active drug shortages reached a record high of 323 as of June 2024 – the highest since tracking began in 2001. These ongoing shortages include basic and life-saving products such as oxytocin, Rho(D) immune globulin, standard of care chemotherapy, pain and sedation medications, and ADHD medications.[5]

The drug shortage crisis continues to escalate. According to IQVIA, over the past five and a half years, approximately 25 new molecule shortages have emerged each year, totaling 160 new molecule shortages by June 2023. Of these, only 51 have been resolved. Furthermore, looking at the time frame of active shortages, three-fourths have been active for over a year, and more than half have been active for over two years.[6]

Drug shortages impose significant costs on the entire health care ecosystem – especially to patients and providers. Patients face delays in care, disease progression, and increased out-of-pocket costs for alternative medications. These challenges lead to worsened health outcomes, counteracting the intended benefits that the pharmaceutical supply chain can provide. In responding to generic drug shortages, health systems and providers face cost hurdles in logistics coordination and increased patient demand for alternative care options.

The U.S. Department of Health and Human Services' Office of the Assistant Secretary for Planning and Evaluation (ASPE) has found that drug shortages are associated with higher direct and indirect costs, including the time and effort patients spend to obtain medications. Additionally, these shortages lead to adverse changes in health outcomes and related care, such as delays in treatment, medication substitutions, lack of treatment, adverse events, and even death. Moreover, there is an equity component, as those who are uninsured or underinsured are more likely to be impacted by these shortages.[7]

A 2019 analysis revealed that due to drug shortages, health systems incur at least $359 million annually in estimated labor resources and $200 million per year to purchase alternative treatments.[8] Additionally, nearly a third of respondents to a 2023 ASHP survey described the current state of drug shortages as critically impactful, forcing patients and providers into dangerous situations where treatments or procedures are rationed, delayed, or canceled. Respondents also estimated that drug shortages add 5% to 20% to their overall budgets.[9]

[5] Drug Shortages Statistics - ASHP
[6] Drug Shortages in the U.S. 2023 - IQVIA
[7] ASPE Report to Congress: Impact of Drug Shortages on Consumer Costs | ASPE (hhs.gov)
[8] HHS - ASPE Report to Congress - Impact of Drug Shortages on Consumer Costs.
[9] ASHP 2023 Drug Shortages Survey Report

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Mitigating risks surrounding generic drug shortages

As previously mentioned, the contributing factors of generic drug shortages are multi-faceted. It is important to note that this white paper primarily focuses on generic drugs due to their widespread utilization by patients, including both generic sterile injectables and generic oral solids.

Short-term solutions

Sustainable and reliable generic drug manufacturing

As part of the debate on generic drug shortages, one factor highlighted by the U.S. Senate Committee on Finance and other industry leaders is the "race to the bottom" in generic drug prices.[10] For the purposes of this paper, we will refer to this issue as "unsustainable pricing," which may be linked to certain market dynamics and reimbursement mechanisms.[10] Cencora advocates for policies that ensure access to safe, effective, and high-quality medications, while also supporting measures that prevent generic drug prices from declining to a level that compromises patient access, drug quality, and safety.

One significant challenge policymakers encounter in addressing the prices of generic drugs is that Medicare does not directly purchase drugs typically administered in physician offices and hospitals; instead, it reimburses the providers who buy those drugs. Consequently, any effective policy solution should incorporate a mechanism ensuring that providers' reimbursement is contingent upon their purchasing behavior—specifically, purchasing drugs from resilient manufacturers at sustainable prices.

Mid-term solutions

Increasing stability of supply

In some instances, drug shortages occur due to unpredictable demand resulting from unforeseen fluctuations and events such as natural disasters, pandemics, and geopolitical crises. These disruptions send shock waves through the drug supply chain, highlighting the urgent need to stabilize and strengthen supply. For instance, when the COVID-19 pandemic began, the demand for many drugs—not just those related to COVID-19—significantly increased as patients sought longer prescription refills due to unpredictable lockdowns and increased prescribing flexibility for providers.[11] This unforeseen surge in demand strained the global supply chain, particularly affecting drugs that were not maintained in adequate strategic vendor-managed inventory or essential medicines reserves. Increasing the stability of demand would assure generic manufacturers that they have a long-term market to rely upon and encourage continued investment in the domestic supply chain and resiliency improvement.

More importantly, pharmaceutical distributors can help solve this issue through a vendor-managed essential medicines reserve. A vendor-managed essential medicines reserve and investments in additional product would help ensure a stable supply of essential generic medicines and other drugs at risk of shortage, which could help prevent shortages from harming patient access to needed essential medicines. A vendor-managed essential medicines reserve would primarily serve as a mid-term solution to the generic drug shortage issue as longer-term solutions are implemented.

[10] White Paper Preventing Drug Shortages (senate.gov)
[11] Drug shortages amid the COVID-19 pandemic. | PSNet (ahrq.gov)

Mitigating risks surrounding generic drug shortages (continued)

Long-term solutions

Improving the resilience of the domestic supply chain and diversification of sources

Addressing barriers for API

The U.S. supply chain for prescription drugs has become heavily reliant on foreign sources of basic and active pharmaceutical ingredients (API), as well as finished and near-finished drug products. Unfortunately, these foreign sources lack diversification.[12] In addition to low diversification, reliance on foreign sources raises national security concerns, particularly for generic drugs that typically have very low-price points.[13] To encourage manufacturers to establish domestic production facilities of both API and finished/near-finished drug products, policymakers must address the need to increase operations in the U.S., compared to lower-cost countries.

Legislation introduced to the 118th Congress, such as the Rolling Active Pharmaceutical Ingredient and Drug Reserve (RAPID) Reserve Act (S.2510/H.R.6802) aimed to enhance supply chain resiliency for critical generic drug products within vulnerable supply chains.[14] This legislation focuses on increasing drug manufacturing in the U.S. and allied countries, while also ensuring that reserves of essential drugs and APIs are maintained to prevent supply disruptions during drug shortages or public health emergencies.

Increasing resiliency is not the only policy justification cited for re-domesticating the U.S. generic drug supply chain. Policymakers from both parties have expressed concerns about national security, public health, and data privacy risks associated with the heavy reliance on foreign sources. This has led to strong bipartisan interest in investing in domestic capabilities and enhancing supply chain resiliency.

However, it is crucial to recognize that, given the significant dependence of the U.S. prescription drug supply chain on foreign sources, attempting to fully re-domesticate the supply chain and relocate all manufacturing to the U.S. is challenging and could lead to major disruptions in sourcing and manufacturing. Instead, the focus should be on encouraging diversification of sources and suppliers while also supporting greater investment in domestic manufacturing and promoting on-shoring and near-shoring where feasible.

Expanding supply chain transparency

To achieve true resilience, it is imperative to ensure transparency into sourcing for basic ingredients, APIs, and finished or near-finished products. Additionally, it is important to expand and standardize across government agencies the definitions of "drug shortage" and "domestic" supply chain (i.e. onshoring or near-shoring). This alignment allows stakeholders – such as the U.S. government and its private partners – to speak the same language while providing a comprehensive, uniform view into the overall U.S. pharmaceutical supply chain.

The ability to view into the domestic supply chain creates opportunities for lower-cost environments to improve resilience without replicating existing concerns related to supply chain concentration and national security or public health risks, such as the impacts of closures on Indian manufacturing facilities.[15]

Legislation such as the Mapping America's Pharmaceutical Supply (MAPS) Act (H.R. 6992/S.2364 in the 118th Congress), would enable the U.S. government, through public-private partnerships, to update the essential medicines list, establish a pharmaceutical supply chain map identifying vulnerabilities, and create a database of such drugs and their affiliated risks. This bipartisan legislation from the 118th Congress lays the foundation for enhancing real-time agility, improving cross-industry operational effectiveness, and allowing U.S. government agencies to integrate actions aimed at reducing risk.[16]

Pharmaceutical distributors, such as Cencora, are rapidly innovating to develop supply chain resiliency mapping tools. These tools leverage existing advanced technological capabilities and access to relevant data sets to look into our upstream pharmaceutical supply chain. Supply chain resiliency mapping empowers the pharmaceutical industry to proactively identify potential risks, foster improved communication and collaboration with suppliers, and inform and deploy robust risk mitigation strategies. In the face of unforeseen events, this solution facilitates rapid response through real-time data analytics and the implementation of contingency plans for agile decision-making and adaptation.

Ultimately, these efforts lead to enhanced supply chain resiliency, ensuring increased product availability, elevated service levels, and timely deliveries to various sites of care and their patients.

Supply chain resiliency mapping empowers the pharmaceutical industry to proactively identify potential risks, foster improved communication and collaboration with suppliers, and inform and deploy robust risk mitigation strategies.

Cencora encourages collaboration with government entities through public-private partnerships to define and establish an intelligent, data driven framework aimed at addressing current and future gaps, and vulnerabilities within the pharmaceutical supply chain.

[12] Geographic concentration of pharmaceutical manufacturing: USP Medicine Supply Map analysis | Quality Matters | U.S. Pharmacopeia Blog
[13] Skyrocketing Pharmaceutical Imports to the U.S. Endanger National Security - Coalition For A Prosperous America
[14] S.2510 - 118th Congress (2023-2024): RAPID Reserve Act | Congress.gov | Library of Congress and H.R.6802 - 118th Congress (2023-2024): RAPID Reserve Act | Congress.gov | Library of Congress
[15] Indian regulator says 36% of inspected drug-making units had to be shut | Reuters
[16] Text - H.R.6992 - 118th Congress (2023-2024): MAPS Act | Congress.gov | Library of Congress

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Cencora's public policy recommendations

Addressing the contributing factors of generic drug shortages requires a holistic, multi-faceted approach. It is not enough to simply address a single policy driver. For example, simply increasing reimbursement for generic drugs that are vulnerable to shortages will not address near or onshoring capabilities; there must also be policy efforts aimed at improving supply chain resiliency and stabilizing both demand and supply as mid-term solutions. Policymakers must address all contributing factors of generic drug shortages concurrently to address the problems causing supply issues for long-term success.

Cencora recommends the following public policy initiatives to address the many causes of generic drug shortages. As previously stated, these solutions are categorized into three main themes: sustainable and reliable manufacturing, supply assurance programs, and tax credits. Additionally, we have indicated whether the solutions should be implemented as short-, mid-, or long-term solutions.

To effectively address the complexities surrounding generic drug shortages, it is essential to ensure that any solution works in tandem to tackle the challenges faced by both manufacturers and providers.

Cencora's public policy recommendations (continued)

Short-term solutions

Sustainable and reliable generic drug manufacturing

"Race to the bottom" pricing and other characteristics of the generics market can render these areas unattractive and unsustainable for manufacturers, while also imposing significant costs on providers, thereby increasing the risk of shortages. To effectively address the complexities surrounding generic drug shortages, it is essential to ensure that any solution works in tandem to tackle the challenges faced by both manufacturers and providers. In 2019, an FDA-led inter-agency Drug Shortage Task Force cited a lack of incentives for manufacturers to produce less profitable drugs as a root cause of drug shortages.[17] Increasing the attractiveness of the generics market, especially for those generics that are at higher risk of shortages, could meaningfully mitigate the shortage issue. There needs to be clear market signals for manufacturers to encourage the production of more generic drugs, enabling providers to deliver equitable and timely care to patients.

To achieve this, Cencora proposes the suspension of Medicaid inflationary rebates to facilitate stable price increases. This measure would help reduce the rate at which generic manufacturers exit the market and enhance competition and provider choices.

Medicaid inflation rebates

For generic drugs that are currently in or at risk of shortage, Congress should suspend Medicaid inflation rebates that hinder stable price increases. This action would decrease the rate at which generic manufacturers exit the market and increase competition and provider choices.

Provider reimbursement incentive

Congress should create a sustainable reimbursement floor for providers purchasing generic drugs from reliable manufacturers and reduce inflation rebate amounts for certain drugs at risk of shortage that qualify for rebate waivers under the Medicare program. This approach would incentivize providers to prioritize reliability solely over the lowest price point thereby increasing demand for more reliable manufacturers and boosting production volume.

Policymakers would create a new reimbursement incentive for specific generic drugs determined as vulnerable to shortages. For example, if a drug goes into shortage, providers would be reimbursed at the average sales price (ASP) +8% rather than the standard 6% minus sequestration. Manufacturers would receive a base price plus a 10% ASP rebate, creating an incentive to increase production of the generic drug in shortage. To ensure that patients have access to a stable and diverse array of generic medications, manufacturers should be required to maintain production consistency.

[17] 2019 Drug Shortages Report, Updated February 21, 2020 (fda.gov)

Manufacturer participant incentive

Congress should create a formulary and reliability bonus program for domestic manufacturers of generic, biosimilar, and "critical" drugs (e.g., those based in the U.S. and U.S. territories). Similar to the previous policy option, this initiative could incentivize providers to prioritize reliability solely over the lowest price point, thereby increasing demand for more reliable production.

Additionally, these policy options would consider both finished and near-finished products, as well as APIs and other intermediary production; even if a final product is manufactured domestically, intermediary production may still occur elsewhere. Ideally, manufacturers would be incentivized to produce goods domestically in a manner that aligns their cost of goods sold with that of foreign-made products.

As previously noted, lawmakers on both sides of the aisle have expressed interest in enhancing domestic supply chain resilience. More importantly, the current supply chain is heavily reliant on foreign sources, making complete domestication unfeasible; however, policy options like this would stimulate increased investment in domestic capabilities and promote the diversification of sources and suppliers.

Legislation has already been proposed to accomplish some of these concerns, specifically the American Made Pharmaceuticals Act (S. 3311 in the 118th Congress). This Act would require the U.S. Department of Health and Human Services (HHS) to conduct a program in at least 8 states that gives preference to U.S.-manufactured generic, biosimilar, and "critical" drugs under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). This preference would affect formulary placement, cost-sharing, Medicaid rebate waivers, Part D star ratings, and Part B bonus payments to providers.

Cencora original public policy

Shortage-Prone Generics Program

Cencora has developed an original policy solution to address the generic drug shortages issue in a multifaceted manner, combining multiple policy options primarily through a reimbursement-based approach while also incorporating a tax credit component. Details on this proposed solution, the "Shortage-Prone Generics Program," are outlined below.

Shortage-Prone Generics Program

Congress should establish the "Shortage-Prone Generics Program" (SPG Program) to define what constitutes a drug "shortage" and an "at-risk" drug across several federal agencies. Additionally, the program would identify key drugs that are currently in shortage or at risk of shortage and create incentives to increase production and stabilize markets. It includes:

- The Secretary of the U.S. Health and Human Services (HHS), in consultation with the U.S. Secretaries of Commerce, Defense, Homeland Security, and Justice (the "Joint Secretaries"), would establish a list of "shortage-prone generic drugs" (SPGs). SPGs are generic drugs that have a history of shortages and are critical to the national security or public health of the United States. The SPGs list would be reviewed annually to determine any additions or deletions from the list.
- Supply chain manufacturers that agree to develop manufacturing sites for inputs or finished versions of SPGs in the U.S., U.S. territories, or other Joint-Secretary-defined "near-shore" countries would become eligible for a sliding scale tax credit ranging from 25%-50%. This credit would vary depending on the scope of the supply chain (e.g. API vs. finished product) and the manufacturing site's versatility in producing multiple SPGs. Eligibility conditions include manufacturers utilizing existing FDA-compliant manufacturing sites and all other applicable federal regulatory agencies; or establishing new manufacturing sites on domestic or "near-shore" soil, or in other countries deemed appropriate, ensuring that such facilities do not pose a national security concern as determined by the Joint Secretaries with input from private sector supply chain stakeholders. Such manufacturers could be referred to as "SPG manufacturers" or "SPGMs."

- The HHS Secretary would maintain and publicly make available a list of SPGMs and the SPGs they produce. Medicare reimbursement for SPGs purchased from SPGMs would be separately payable to providers, instead of being reimbursed through the standard inpatient prospective payment system (IPPS) bundled payment, outpatient prospective payment system (OPPS) packaged payment, or physician fee schedule (PFS) average sales price (ASP) methodologies. Reimbursement would be based on the SPG's non-aggregated ASP plus an add-on percentage (the "SPG ASP") to help offset the costs incurred by provider in complying with the conditions for receiving the SPG ASP payment.
- The SPG ASP add on would equal ASP +8% compared to the current ASP +6% minus sequestration.
- As a condition of receiving the SPG ASP, providers would be required to agree to a "sustainable contract" with the SPGM. A "sustainable contract" would include:
  - Offering the SPGM a minimum 2-year contract to purchase SPGs at the ASP price (minus the add-on, which the provider would retain) as of the contract execution date; or
  - Providing the SPGM with an alternative assurance of demand, such as a monthly subscription "Netflix" model that guarantees a fixed payment for the SPG regardless of actual utilization.
- Participating SPGMs whose SPGs experience list price increases above inflation due to the SPG Program would be exempt from inflation rebate penalties in both Medicare and Medicaid.
- SPGMs and their SPGs would be subject to the same FDA approval and inspection requirements as all other drug manufacturers.
  - SPGMs would also be subject to increased transparency requirements to provide the FDA with greater visibility into their supply chains.
- SPGMs must commit to partnering with the pharmaceutical distribution industry to ensure access to medications at all sites of care.

Cencora's public policy recommendations (continued)

Mid-term solutions

Increasing stability of supply: Supply assurance programs

Unexpected changes in demand and unpredictable events – such as natural disasters, pandemics, and geopolitical events[18] – can often lead to shortages of essential medicines. Establishing an essential medicines reserve in anticipation of supply and demand shocks would help mitigate these impacts and prevent short-term shortages.

From a national security and defense perspective, creating a vendor-managed essential medicines reserve of critical medications should be prioritized as a defense strategic priority to enhance global positioning and security. As mentioned earlier, this inventory would serve as a mid-term solution while longer-term strategies to address drug shortages issues are developed and implemented.

Additionally, while pharmaceutical distributors are well-positioned to play a key vendor role in this solution, maintaining such an inventory is feasible with external support, such as government investment and partnership.

Essential Medicines Reserve (EMR)

Until the supply chain incorporates enough manufacturing redundancy to address potential supply and demand scenarios in real-time, maintaining a reserve of essential medications for supply-driven shortages is a necessity. Given that most providers lack the necessary infrastructure and logistics expertise to effectuate medication reserves, we propose that pharmaceutical distributors serve as key operational partners to rapidly deploy secure, efficient and scalable models.

Some proposed legislation includes a policy solution designed to enhance stability by guaranteeing generic manufacturers a minimum market threshold through the establishment of an essential medicines reserve (EMR).

This approach would build on the precedent established by the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 during the COVID-19 pandemic, which mandates continuing guidance from the U.S. Food and Drug Administration (FDA). This guidance requires pharmaceutical manufacturers to have contingency plans to respond to drug shortages, particularly of generic drugs.

A U.S. Department of Health and Human Services (HHS) pilot vendor-managed inventory program would serve this purpose, in partnership with private supply chain experts, for a reliable supply of essential medicines. Legislation has been proposed to accomplish this, namely the Essential Medicines Strategic Stockpile Act (EMSSA) (H.R. 405 in the 118th Congress). This Act would require HHS to conduct a pilot program to create such a vendor-managed inventory of generic drugs at risk of shortage through a vendor management program. HHS would enter contracts with manufacturers, wholesalers, co-op or chain pharmacy warehouses, or other eligible entities to establish a six-month stockpile of up to 50 generic drugs identified as vulnerable to shortages.

In a similar vein, a pilot program to establish an essential medicine strategic vendor-managed inventory within the U.S. Department of Defense (DoD) would play a vital role in mitigating supply-driven drug shortages, particularly of shortages caused by unexpected circumstances like geopolitical events. Policymakers could mandate that the DoD establish a pilot program that leverages the existing operations of DoD's pharmaceutical prime vendor program. This program would utilize private pharmaceutical distribution to acquire, manage, and replenish supplies of certain generic medications at risk of shortage within the military health system, ensuring stability in the face of pharmaceutical supply disruptions.

Medicare Conditions of Participation

To prevent exits from the generic market, the Centers for Medicare & Medicaid Services (CMS) should amend the Medicare Conditions of Participation (CoP) to require all providers and hospitals—particularly those identified through the CMS Inpatient Prospective Payment System (IPPS) rule—to implement an inventory and provider generic drug shortage prevention plan. This plan should be reviewed, revised, and approved annually by the CEO of U.S. hospitals and health systems. Such a requirement would promote and ensure widespread adoption, standardization, and stabilization of shortage-prone generic manufacturers (SPGMs) within the market.

The prevention plan would incorporate several specific elements to effectively address potential shortages of essential generic medications. This includes identifying a priority list of essential generic drugs at risk of shortages, establishing a vendor-managed essential medicines reserve with contracts for inventory maintenance, and developing clear contracting procedures. These procedures should consider supplier quality, diversity of supply, and committed volume, ensuring that healthcare providers are well-equipped to manage their inventories efficiently.

By implementing such a prevention plan, providers would be better prepared for unexpected disruptions to pharmaceutical inventories at their sites. Proactively addressing potential shortages would help mitigate the impact of supply chain disruptions before they escalate to critical levels, ultimately safeguarding patient care and ensuring the availability of essential medications.

In 2023, more than 99% of hospital and health system pharmacists reported experiencing drug shortages, highlighting a critical issue in healthcare.[19] Pharmaceutical distributors are uniquely positioned to address this challenge by rapidly expanding the availability and types of medications through drug shortage mitigation initiatives designed to provide health systems with reliable access to critical medications, including those at risk of shortage. Pharmaceutical distributors are willing and able to collaborate with the U.S. and state governments through a public-private partnership; however, they require increased, funding to support the sourcing, storage, and administration of shortage-prone and alternative pharmaceuticals. This funding is essential for encompassing a wide range of therapeutic classes and disease states.

To ensure that no provider has to delay or skip operationally critical treatments for patients due to supply gaps, the establishment of essential medicine reserves is vital. These reserves would guarantee providers have reliable access to necessary medications when they need them, ultimately safeguarding patient care and enhancing the overall resilience of the healthcare system. By promoting provider participation and incentivizing collaboration, the healthcare system can more effectively mitigate drug shortages and maintain continuity of care. This proactive approach would not only address immediate supply concerns but would foster a more robust framework for managing future drug shortages, ultimately benefiting both providers and patients alike.

[18] Drug shortages: A guide to policy solutions | Brookings
[19] Drug Prices and Shortages Jeopardize Patient Access to Quality Hospital Care | AHA News

Cencora's public policy recommendations (continued)

Long-term solutions

Improving the resilience of the domestic supply chain and diversification of sources: Tax incentives

Pharmaceutical manufacturing has significantly moved overseas for lower costs and greater regulatory flexibility, complicating efforts to create reserves and increase production to mitigate shortages, often due to associated costs like environmental and labor regulations.[20] Offering tax incentives to encourage manufacturers to invest in resilient and sustainable practices – especially in strengthening the domestic supply chain – would better enhance solutions to mitigate drug shortages.

Tax incentives related to essential medicine reserves and manufacturing capacity

Provide a tax incentive for domestic generic drug manufacturers to increase manufacturing capacity for drugs likely to experience shortages.

For instance, this could take the form of tax incentives for generic manufacturers based in the U.S. and its territories (and potentially other nations or regions as deemed appropriate). The proposed incentives would come with specific requirements for increasing production capacity of certain drug ingredients and finished products deemed vulnerable and critical.

Legislation has already been proposed that reflects this concept, specifically the Rolling Active Pharmaceutical Ingredient and Drug (RAPID) Reserve Act (S.2510 in the 118th Congress). This legislation leverages HHS contract awards to support drug manufacturers.

However, it could be modified to convert the HHS contracts into tax incentives for manufacturers. The Treasury could make payments of grants in lieu of tax incentives to eligible entities. This approach would provide immediate financial support particularly to generic drug manufacturers who commit to holding reserves and increasing production capacity for critical drugs and active pharmaceutical ingredients (APIs).

Tax incentives related to increased U.S. production

Establish tax incentives for drug manufacturers to produce drugs in disadvantaged areas in the U.S. and its territories (Commonwealth of Puerto Rico) to improve resiliency, like tax advantaged enterprise zones. Tax incentives designed to encourage manufacturers to invest in finished and near-finished products, APIs, or other intermediary production in disadvantaged areas of the U.S. would increase domestic pharmaceutical production, thereby improving the resilience of the domestic supply chain. This comprehensive approach, along with meaningful policies strives to create a sustainable manufacturing environment that benefits both the pharmaceutical industry and economically challenged communities. Ultimately improving the nation's healthcare resilience and national security.

Legislation has already been proposed to accomplish this goal, namely by the Manufacturing API, Drugs, and Excipients (MADE) in America Act (H.R. 2707 in the 118th Congress). This Act would create a "distressed zone pharmaceutical and medical device production" tax credit for pharmaceutical or medical device manufacturers operating in certain Opportunity Zones across the United States.

Similarly, providing tax incentives to generic drug manufacturers to boost U.S. production through a modified version of the Creating Helpful Incentives to Produce Semiconductors (CHIPS) and Science Act of 2022 would promote domestic production. These incentives should apply to finished and near-finished products, APIs, or other intermediary production.

The CHIPS Act established a tax credit for semiconductor manufacturers to promote increased domestic production over several years. Comparably, a modified version of the CHIPS Act would create a tax credit for domestic generic drug manufacturing, aimed at offsetting costs associated with investing in facilities that manufacture generics in the U.S. This credit should be refundable and available to generic manufacturers operating in the U.S. and its territories.

Tax incentives for generic drug manufacturers seeking Abbreviated New Drug Applications (ANDAs) approval

ANDAs are the process in which manufacturers apply to the FDA to produce generic drugs; developing an ANDA for a generic injectable drug and obtaining FDA approval costs a manufacturer roughly $3 million.[21] This can be viewed as overly costly by manufacturers, especially given the low profitability in many generics markets. Policy considerations should look at finished products, APIs, and other intermediary production.

To address the anticipated increase in ANDA applications from generic manufacturers, the FDA should establish a commission to manage application volume and develop eligibility requirements to expedite ANDA approvals. This would streamline efficiency and enhance U.S. production.

Policymakers would establish a tax incentive for generic manufacturers that agree to pursue ANDA approval for generic drugs—particularly finished products—that the U.S. Department of Health and Human Services (HHS) Secretary identifies as vulnerable to shortages. Furthermore, generic manufacturers would be required to guarantee the production of these drugs occurs within the U.S.

The proposed tax incentives are designed to address the challenges of drug shortages and bolster domestic pharmaceutical production by encouraging manufacturers to invest in resilient practices and hold essential medicine reserves to mitigate supply chain and treatment disruptions. Collectively, these strategies will strengthen the U.S. healthcare system, improve national security through a reliable supply of essential medicines, and most importantly increase patient access and sustainability without compromising provider choice and pharmaceutical quality.

[20] Safeguarding Pharmaceutical Supply Chains in a Global Economy - 10/30/2019 | FDA
[21] Civica-Coukell-testimony-EandC-14SEP2023-FINAL.pdf (civicarx.org)

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Conclusion

Combined, these policy recommendations would meaningfully address the many multifaceted factors contributing to generic drug shortages, ensuring a more stable and resilient supply chain and healthcare system.

As policymakers work to address generic drug shortages and strengthen the U.S. pharmaceutical supply chain, Cencora remains a partner of choice in developing robust policy solutions. Drawing from our integral role in the pharmaceutical supply chain, we are committed to offering valuable insights to policymakers and supply chain partners. We look forward to continuing our engagement with key stakeholders and the U.S. government as we work together to address the critical issue of the impact of generic drug shortages on patient access and care in the U.S. and beyond.

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About Cencora

Cencora, formerly AmerisourceBergen, is a leading global healthcare company, with a foundation in pharmaceutical distribution and solutions for manufacturers, pharmacies, and providers. We create unparalleled access, efficiency, and reliability for human and animal health. Tens of thousands of healthcare providers, veterinary practices and livestock producers trust us as their partner in the pharmaceutical supply chain. Global manufacturers depend on us for services that drive commercial success for their products. Our 46,000 global team members power our purpose:

We are united in our responsibility to create healthier futures.

At Cencora, and through our family of companies, we ensure that crucial medications efficiently, reliably, and securely reach health care providers, pharmacies, hospitals, veterinary practices, and clinics every day. Cencora has a legacy of more than 100 years of excellence in pharmaceutical supply chain operations, sourcing, and distribution. **Cencora's role in the pharmaceutical supply chain and robust expertise provide us with a unique and heightened perspective on policy solutions that can help address the causes of generic drug shortages.**

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