

Executive summary

Cencora's U.S. generic drug shortages public policy recommendations

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

- 1 Challenges to diversification and sourcing of active pharmaceutical ingredients (API)
- 2 Disruptions impacting the generic supply chain
- 3 Uncertainty of the generic drug manufacturing market
- 4 Limited visibility into global mapping of generic medications
- 5 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.

Overview of Cencora's public policy recommendations (continued)

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 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 2023 (P.L. 117-167)
- Generic drug manufacturers to seek FDA's 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 U.S. government to tackle the critical issue of generic drug shortages affecting patient access and care both in the U.S. and beyond.

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 many causes of generic drug shortages.



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