

## **Senate Finance Committee Discussion Draft: Preventing & Mitigating Generic Drug Shortages**

### **Overview of the Problem**

Shortages in the supply of prescription drugs present a persistent and growing challenge in the United States, resulting in worse outcomes and higher costs for patients and the health care system. This month, the American Society of HealthSystem Pharmacists (ASHP) announced that drug shortages have reached an all-time high—with 323 medicines now in short supply. Generic drugs comprise the majority of medications in shortage at any given time, and a recent analysis found that 56 percent of drugs in shortage in 2023 cost less than \$1 per unit. Generic injectables have proven particularly vulnerable, representing an estimated 67 percent of shortages overall.

### **Summary of Discussion Draft**

The Senate Finance Committee has developed bipartisan legislation to prevent and mitigate generic drug shortages across the U.S. using the power of the Medicare and Medicaid programs. Specifically, the Committee’s draft proposal would: (1) establish new authority and resources within Medicare to reform provider (hospital and physician) purchasing of generic drugs at high risk of shortage; and (2) modify the Medicaid program to allow generic manufacturers to address economic challenges creating shortages for numerous retail drugs.

Beginning in 2027, a new **Medicare Drug Shortage Prevention and Mitigation Program** would leverage targeted provider payment incentives to promote improvements and reforms in contracting and purchasing practices across the supply chain that enhance resiliency, reliability, and sustainability, with a focus on generic drugs confronting high shortage risks, beginning with generic sterile injectables (such as saline used in hospital settings) and infused medications (such as chemotherapy), with the potential for expansion to additional multiple-source drugs over time. Under the voluntary program, with respect to participating providers, manufacturers, and other entities, the following requirements would apply:

- **Program Participation:** Program participants (such as group purchasing organizations (GPOs)) must adopt purchasing and contracting practices that meet new standards for supply chain resiliency, reliability, and transparency in order for health providers to receive new Medicare payment incentives. The proposal also enables providers, if they opt to do so, to participate directly. Generic manufacturers, in turn, would become eligible suppliers, for program purposes, by entering into Manufacturer Reliability Agreements. Under the draft, statutory terms and standards would be included in agreements among participating entities.
- **Core and Advanced Standards:** Providers must meet minimum **core standards** related to generic drug contracting and purchasing to be eligible for Medicare incentive payments, including minimum three-year contracts with manufacturers, meaningful purchase volume commitments and stable pricing. Requirements for contingency contracts with alternate manufacturers and transparency around manufacturer quality control issues would also be included with the core standards, and repeat violations of requirements could result in participant lockout from the new program. Certain **advanced standards**, related to factors like advanced manufacturing technology and domestic manufacturing, would yield additional incentive payments.
- **Incentive Payments for Participating Health Care Providers:** If core standards are met with respect to a given generic drug, providers would be eligible for **quarterly, lump-sum incentive payments**, calculated as a percentage of a price benchmark and scaled up based on compliant purchase volume. Achievement of **advanced standards** for a given product would yield **add-on percentage-point payments**. Separately, a **bonus pool** would finance high-performing providers (relative to peer provider cohorts) based on **outcome measures**.

Additionally, beginning in 2027, the application of inflation rebates would be targeted to sole-source generics under the **Medicaid Drug Rebate Program's (MDRP's) generic drug inflation rebate provisions** in order to mitigate pharmacydispensed (retail) generic drug shortages. Similar to the Medicare inflation rebate program, the HHS Secretary could reduce or waive inflation rebates in the event of generic drug shortage risk. The proposal would fully offset the resulting costs through an increase in the MDRP's basic rebate amount for generics in order to keep state Medicaid programs whole while improving economic predictability and sustainability for high-shortage-risk generic drugs.