

Drug Shortages: Policy Update

BY NICOLE TAPAY, JD



Several important oncology medicines remain in short supply in 2024 and the potential for additional and/or more severe shortages remains. ACCC continues its work with a coalition of patient advocacy and provider organizations, led by the Hematology/Oncology Pharmacy Association (HOPA), to examine causes of and systemic challenges highlighted by the shortages and to consider proposed policy solutions. This work has included the opportunity to meet with Congressional staff as they draft possible proposals in both Houses. Meanwhile, below are highlights of important policy developments in Congress and at the Department of Health and Human Services (HHS).

Senate Finance Committee Proposal

On May 3, 2024, the Senate Finance Committee released draft legislation to address drug shortages in the generic market, using tools and incentives created within the Medicare and Medicaid programs. The legislation focuses on generic sterile injectables and infused medications, such as chemotherapy. It sets up a new Medicare Drug Shortage Prevention and Mitigation Program and establishes incentives for program participants (such as Group Purchasing Organizations [GPOs], although providers could also participate directly) and providers that meet certain core standards. Under the proposal, generic manufacturers become eligible suppliers if they enter into agreements that meet statutory requirements. The bill also authorizes the HHS Secretary to waive inflation rebates under the Medicaid drug rebate program if there is a risk of a generic drug shortage.

Payment-eligible providers include hospitals, physician practices, and other providers who furnish items and services, including applicable generics, to Medicare beneficiaries, enter into agreements meeting program requirements, and comply with reporting and other requirements. Providers must enter into agreements with a minimum of three-year terms and meet volume and pricing requirements. They also must enter into agreements with secondary manufacturers. Certain advanced standards, such as advanced manufacturing technology and domestic manufacturing, would yield additional incentive payments. The legislation offers the potential for participating providers to receive quarterly incentive payments, and providers who meet advanced standards could receive more payments. Additionally, the bill creates a bonus pool to finance high-performing providers based on outcome measures.¹

ACCC Action: ACCC has conveyed its support of the proposal to the Senate Finance Committee.

HHS Proposals

The Administration has also released policy proposals to address this serious issue.


On April 2, 2024, HHS issued a [white paper](#) on drug shortages.² It details existing or ongoing agency actions to address shortages, including the establishment of a Supply Chain Resilience and Shortage Coordinator role and efforts to facilitate greater transparency in the market and investments by the Agency for Strategic Preparedness and Response to support active pharmaceutical manufacturing. The white paper also explores possible ways to promote domestic production of medicines. In addition, the paper includes proposals for

two new programs:²

1. The Manufacturer Resiliency Assessment Program, a public-private partnership to measure generic manufacturer resilience and improve transparency
2. A new Hospital Resilient Supply Program to facilitate hospital purchasing that prioritizes supply chain resilience and could include incentives and/or penalties. This program would begin with a focus on inpatient hospitals. The white paper notes that, if successful, the program could expand to the outpatient setting or include medical devices.

On April 10, 2024, the Centers for Medicare & Medicaid Services (CMS) issued the Fiscal Year 2025 Inpatient Prospective Payment System proposed rule, which includes a proposal for a separate payment for small, independent hospitals to establish and maintain a buffer stock of essential medicines.³ In its comments to CMS, ACCC did not support the idea of a buffer stock; it is unclear why there is a focus on the inpatient setting in these recent policy proposals.

HHS has also released a request for information with the Federal Trade Commission to better understand the causes of the generic drug shortages.

ACCC Action: ACCC will continue to monitor policy developments and weigh in, on its own and with coalition partners, with its input and expertise. 

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References

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