



Healthcare Distribution Alliance

HEALTH DELIVERED

Chester "Chip" Davis, Jr., President and Chief Executive Officer

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Polly Webster
Senior Health Counsel
Chairman Ron Wyden
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Conor Sheehey
Senior Health Policy Advisor
Ranking Member Mike Crapo
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Ms. Webster and Mr. Sheehey,

We appreciate the opportunity to provide feedback and offer insights on the *DRAFT Medicare Drug Shortage Prevention and Mitigation Program*. The Healthcare Distribution Alliance (HDA) is the national organization representing primary pharmaceutical distributors. HDA advocates on behalf of pharmaceutical wholesalers and distributors, leads the sector on relevant policy, and fosters relationships across partner organizations. As the Senate Committee on Finance and its staff continue to examine the issue of drug shortages, we thank you for the thoughtful draft program to address multi-source injectable and infusible drug shortages. As the committee continues to address drug shortages, HDA and its members welcome the opportunity to continue a dialogue with committee members and staff.

HDA and its members appreciate the committee's effort to address drug shortages, specifically the largest single category of shortages, generic sterile injectable (GSI) products. HDA has [previously commented](#) on shortages of GSIs, as this product category accounts for [67%](#) of current drug shortages¹. While the specifics of each drug shortage are unique, reliability issues² and market exits³ have emerged as recurring drivers of shortages. Because of the varied factors that contribute to a drug shortage, it is difficult to devise a program that would address all the key factors of various shortages. To that end, focusing the scope of this draft program on generic sterile injectables, specifically those used in the acute care setting, could address a significant portion of the drug shortages.

Applicable generics

The program appropriately focuses on multi-source generic injectable and infusible drugs. We would recommend a process to develop the list of applicable generics through an expert panel,

¹ Avalere. Drug Shortages: Landscape Assessment of Policy Proposals to Prevent and Mitigate Drug Shortages. Published 2024. <https://avalere.com/wp-content/uploads/2024/01/Drug-Shortages-Whitepaper-1.25.2024.pdf>.

² Healthcare Distribution Alliance. HDA RFI Submission Drug Shortages. Published 2023. <https://www.hda.org/getmedia/cc3658b0-cebe-47cd-a944-0af2504ece9a/HDA-RFI-Submission-Drug-Shortages.pdf>.

³ IQVIA. Drug Shortages in the U.S. 2023: A Closer Look at Volume and Price Dynamics. Published 2023. <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/drug-shortages-in-the-us-2023/drug-shortages-in-the-us-2023.pdf>.

including members of the private sector and supply chain. The scope of this program would be most impactful if it applies to products that are at high-risk of shortage due to market factors which would be stabilized through an incentives-based approach. Current essential medicines lists that have been developed would not apply to this program, so we would recommend a separate process to determine which GSI products would be stabilized through the creation of the shortages mitigation program.

Incentives

The draft drug shortage mitigation program seeks to provide incentives to providers based on certain supply chain management decisions such as purchasing volume guarantees and long-term contracting. It is necessary to consider what parameters need to be specified in the program to allow for a certain amount of off-contract purchasing, as this capability is important to maintain robust markets. Without a certain level of off-contract purchasing, new manufacturers are unable to enter the market for a product. Further, we agree that it is necessary to create these types of incentives for providers to maintain these practices, and would urge the committee to consider what, if any, additional incentives or investments need to be provided to manufacturers, group purchasing organizations (GPOs), and wholesalers in order to ensure their participation in the program is sustainable. As an example, the [buffer inventory](#) advanced standard would require funding in order for a distributor to maintain the three- or six-month product inventory, preferably based in the United States. HDA is [very supportive](#) of strategies to add more buffer in the system through strategic stockpiling in partnership with facilities, and recognizes the funding required to maintain this capability.

Role of wholesalers

The draft drug shortage prevention and mitigation program includes thoughtful policies that involve many key components of the supply chain: GPOs, distributors, payment-eligible providers, and manufacturers. We would welcome more insight into the decision to leverage Medicare Part E in this program, especially with the focus of the program being generic sterile injectables in the acute care setting. This insight would help inform recommendations for the role of wholesalers in such a program.

The program outlines eligible program participants through a voluntary participation agreement and adhering to the core standards (and possibly the advanced standards). We are concerned that as written, the core and advanced standards apply to some stakeholders but not to others, which could lead to confusion and difficulty in determining which standards apply to each program participant. We recommend developing different standards for GPOs, wholesalers, and providers, recognizing that each stakeholder plays a different role in the implementation of the program.

Impact of program

In addition to reviewing the potential for this program to mitigate shortages, HDA and its members believe that it is also prudent to consider how this program would impact the response to a shortage of a product in the program. We urge the committee to consider how this program would impact purchasing and contractual commitments during a shortage. In order to ensure distribution of medical products during a shortage, it would be important to allow distributors to continue the use of pre-existing best practices such as their allocation programs and other inventory management tools without penalty.

Creating a drug shortage prevention and mitigation program through Medicare Part E is innovative and could help to stabilize some GSI drugs for the acute care setting. As we consider the proposal, we welcome additional discussions on the specifics of the program, and details that would impact the success of the proposed drug shortage prevention and mitigation program.

HDA and its members thank the Senate Committee on Finance staff for the thoughtful and bipartisan work to address drug shortages. We stand ready to provide our continuing perspective on the complex dynamics associated with drug shortages and offer our [policy recommendations](#) and [insights](#). If you have any questions or would like additional information, please contact me directly at cdavis@hda.org or (302) 438-4751.

Sincerely,

A handwritten signature in cursive script that reads "Chester W. Davis, Jr.".

Chester "Chip" Davis, Jr.