HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

June 6, 2024

Chairman Ron Wyden
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Ranking Member Mike Crapo
Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chair Wyden and Ranking Member Crapo,

We appreciate the opportunity to provide feedback on the Senate Committee on Finance's discussion draft, *Drug Shortage Prevention and Mitigation Act*. The Healthcare Distribution Alliance (HDA) is the national organization representing primary pharmaceutical distributors. HDA advocates on behalf of pharmaceutical distributors, leads the sector on relevant policy, and fosters relationships across partner organizations. We thank the Senate Committee on Finance and its staff for the thoughtful discussion draft to address generic drug shortages. As the committee continues to examine 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 efforts to prevent and mitigate generic drug shortages. HDA has previously commented on the committee's work to address drug shortages and offered distributor insights into economic dynamics that impact parts of the generic market. The unique role that distributors serve in the market provides some perspective into market factors, including those that lead to drug shortages. HDA welcomes the committee's efforts to consider financial incentives and their role in developing sustainable solutions to address drug shortages.

Medicare Drug Shortage Prevention and Mitigation Program

Program Framework

The discussion draft states that program participants must apply for and agree to Program Participation Agreements, which we expect the Centers for Medicare and Medicaid Services (CMS) will determine in rule-making.

The discussion draft requires applicable generic manufacturers to report Average Sales Price (ASP), even if they do not have ASP-reimbursed drugs. This requirement creates a False Claims Act (FCA) risk for generic manufacturers that do not have ASP-reimbursed drugs. We would encourage the committee to revise this section to scope only for ASP-reimbursed drugs.

To ensure that the applicable generics chosen are vulnerable to shortage, HDA and our members recommend a process for developing the list of applicable generics through an expert panel. The

expert panel should include members of the private sector and pharmaceutical supply chain, such as distributors, pharmacies and providers who understand the need for redundancies for products where current market dynamics add rigidity to supply chains. The expert panel can also examine the developed list of applicable generics to identify strategies that can bolster operational resilience. Those strategies may protect investments in domestic manufacturing and national security, preventing shortages.

Implementation Factors

As a condition of participation, participants must report to CMS and submit to periodic audits from the Department of Health and Human Services (HHS) Secretary. We encourage the committee to be mindful of the administrative burden on program participants as the program is structured and explore strategies to minimize it for all participants, especially those involved in direct patient care. HDA and our members encourage the committee to consider adding language to utilize the auditing process to review business sensitive information, rather than requiring it in a report. Without exemptions, proprietary and confidential information provided in reports would be made publicly available on CMS' website and could be eligible for Freedom of Information Act (FOIA) requests. Further, HDA encourages HHS to confidentially hold all business sensitive information collected from reporting and exclude it from publication on HHS's website.

HDA and our members suggest including language clarifying the role of the Food and Drug Administration (FDA) in this program, as the current consulting role of the FDA is unclear. The FDA does not have existing authority over or cooperation within a CMS program. We recommend language on the scope of the FDA's engagement within the program and how the FDA will interact with CMS and program participants.

Standards / Compliance

The Medicare Drug Shortage Prevention and Mitigation Program seeks to provide incentives to payment-eligible providers based on core and advanced standard and outcome measures. Program participants must comply with and meet standards for payment-eligible providers to receive incentive payments.

We are pleased to see incentives for meeting standards; however, many core and advanced standards do not apply to all program participants. As currently written, the majority of the core and advanced standards primarily apply to manufacturers. As a result, we seek to work with the committee to establish appropriate standards for potential distributor program participants. In addition, we recommend developing different standards for Group Purchasing Organizations (GPOs), distributors, manufacturers, hospitals, and providers, recognizing that each plays a distinct role in implementing the program. Program standards should preserve each stakeholder's existing key capabilities that create resilience in the supply chain. To ensure sustainable participation, we recommend that the committee include clear incentives for all program participants connected to compliance with standards. To preserve resilience and diversity in the supply chain, we ask the committee to consider the impact of the core standards on new market entrants (on the manufacturing side). The current volume requirements and off-contract purchasing limitations may prevent new manufacturers from entering the market. We appreciate the flexibility the program provides for core and advanced standards in the event of a supply chain disruption or event. HDA and our members encourage the committee to include language defining "upward price adjustments".

HDA supports strategies to add more buffer inventory to the system through strategic or regional stockpiling programs in partnership with the private sector, which requires funding to establish and maintain. HDA has previously expressed concerns about buffer inventory proposals that do not account for equitable access to products. Distributors are uniquely positioned in the supply chain to assist hospitals, health systems, physician clinics, pharmacies and states with maintaining a robust inventory as a part of their supply chain management practices. We support proposals that leverage existing infrastructure, recognizing that pharmaceutical distributors have the necessary physical and logistical expertise. In the discussion draft, buffer inventory standards do not include specific incentive payments for a third party, such as distributors. The buffer inventory standards also do not clarify if distributors can use pre-existing inventory management best practices, such as equitable allocation, without penalty. We recommend that the committee consider adding language allowing third parties to maintain inventory management capabilities.

HDA supports strategic domestic manufacturing investments that create supply chain redundancies and addresses geopolitical risks. While domestic manufacturing may increase national security and geographic diversity, it may impact resilient infrastructure, but not necessarily drug shortages.[1] As written, there is concern that the program would not cover the cost realities of domestic manufacturing, making this standard unsustainable for pharmaceutical supply chain stakeholders. We acknowledge that domestic manufacturing is a potential strategy for a limited number of product categories critical to supporting national security. Congress has a precedent of supporting domestic manufacturing through tax credits[2], and recent efforts[3] to incentivize domestic production, which are yet to be fully realized. Without financial incentives, manufacturers have little incentive or ability to invest in reshoring production capabilities for active pharmaceutical ingredients, key starting materials, and finished dose forms.[4]

Participating providers will also be eligible to receive outcome measure incentive payments based on their performance in preventing and mitigating applicable generic shortages during a program year. We encourage the committee to include language on how the performance of other program participants will be factored into the outcome measures, and what factors CMS should prioritize or consider when evaluating outcome measures.

HDA and our members agree that it is necessary for payment-eligible providers to receive incentives. However, the program should provide additional incentives to other participants to ensure sustainable program participation. We recommend that the committee also consider the role incentives play in preserving stakeholder resilience practices.

Rebates for Generic Covered Outpatient Drugs Under Medicaid

HDA appreciates the committee's work to address drug shortages in both the hospital and outpatient settings. Drugs in the outpatient setting are often in shortage due to different drivers than the supply-

[1] Healthcare Distribution Alliance. HDA Guiding Principles for Drug Shortages. Published 2024. https://www.hda.org/getmedia/a6382b52-17f5-49b2-907b-7838847d867c/HDA-Drug-Shortages-Guiding-Principles.pdf.

[2] Public Law 112-114 (GAIN Act). Published July 9, 2012. https://www.congress.gov/112/plaws/publ144/PLAW-112publ144.pdf.

[3] Public Law 117-167 (CHIPS Act). Published August 9, 2022. https://www.congress.gov/117/plaws/publ167/PLAW-117publ167.pdf.

[4] Association for Accessible Medicines. A Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain. 2nd Edition. Published October 2021. https://accessiblemeds.org/sites/default/files/2020-04/AAM-Blueprint-US-Pharma-Supply-Chain.pdf.

drivers that impact hospital products, specifically the drivers that impact the generic sterile injectables market.[5]

We understand the intent of the policy alleviating rebate obligations in the Medicaid Drug Rebate Program (MDRP) is to alleviate strain on manufacturers at risk of shortage in a highly competitive market. Currently, the policy focuses on risks to single source generics. However, recent IQVIA data has revealed that drug shortages occur more often in multi-source generic products than for single-source generics, highlighting a need to focus on stabilizing multi-source products prone to shortage.[6] Single-source generics in shortage represent seven percent of the market whereas multi-source generics in shortage represent nine percent[7]; reflecting the need to address both.

We encourage the committee to clarify whether there would only be inflation rebates on single-source generics and if this can be waived in the event of a shortage, a policy supported by other supply chain stakeholders. We appreciate this clarification, recognizing the strain experienced during a drug shortage event[8].

HDA encourages the committee to consider a study to determine the impact of the policy change on the cost of retail-administered products at risk of shortage, as well as the price threshold for exemption (currently at $100 in the discussion draft). HDA and our members are concerned about the potential for the applicable percentage of the Average Manufacturer Price (AMP) policy. This policy will result in higher prices for purchasers, which would counter the existing incentives to participate in the program.

Impact on Drug Shortages

The scope of the Medicare Drug Shortage Prevention and Mitigation 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. We encourage the committee to look at single-source and highly concentrated multi-source generic molecules, which have been demonstrated to be a more vulnerable segment of the manufacturing sector.[9] Over three-quarters of current shortages are in highly-concentrated markets.[10] When examining multi-source generic molecules, it is important to consider that multi-source does not always translate into the ability for suppliers to fill gaps due to a competitor's shortage.[11]

We urge the committee to consider how the program would impact purchasing and contractual commitments during a drug shortage. It is essential to allow distributors to continue using pre-existing best practices, such as their equitable allocation programs and other inventory management tools, without penalty to ensure the distribution of products during a shortage. We ask the committee to include language to preserve distributors' abilities to manage buffer inventory using their existing inventory management tools.

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[5] 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.

[6] 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.

[7] Ibid.

[8] Ibid.

[9] Ibid.

[10] Ibid.

[11] Ibid.

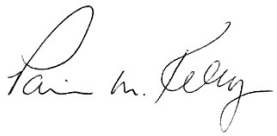
As written, the MDRP rebate policy does not require manufacturers with an MDRP rebate exemption to invest in resilience. The MDRP policy may create a more favorable environment by increasing revenue for manufacturers with products at risk of shortage. Though not guaranteed, the MDRP policy may reduce inflationary pressures and create a more sustainable market for the products with rebate exemptions.

As HDA considers the discussion draft, we welcome additional discussions on the specifics of the proposed policies and details that would impact the success of the proposed program and MDRP rebate policies.

Conclusion

HDA and its members thank Chairman Wyden, Ranking Member Crapo and the Senate Committee on Finance staff for their continued thoughtful and bipartisan work on 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 pkelly@hda.org.

Sincerely,



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