HDA
Healthcare Distribution Alliance
HEALTH DELIVERED

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1808-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Docket No. CMS-1808-P; Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes

Dear Administrator Brooks-LaSure,

The Healthcare Distribution Alliance (HDA) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments to its annual Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals Proposed Rule.[1] HDA's comments herein focus on CMS' proposal within the Proposed Rule that would establish a payment adjustment for the additional resource costs that small, independent hospitals incur in establishing and maintaining access to a 6-month buffer stock of one or more essential medicine(s) (the "proposal").

HDA represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently.

HDA continues to support diversified solutions to drug shortages, especially as the causes of these shortages are multifaceted and treatment specific.[2] Indeed, the causes for shortages are broadly categorized as either manufacturer/supply-driven or consumer/demand-driven. Supply-driven shortages are triggered by unavailability of raw materials or active pharmaceutical ingredients, manufacturer disruptions, or quality issues at the manufacturer facility. In contrast, demand-driven shortages are caused by medical surges or other increases in demand that create a sudden uptick in ordering.[3]

Given the different causes, solving the issue of drug shortages requires a whole-of-government approach.[4] We appreciate CMS' buffer stock proposal as a solution within the agency's purview and

[1] 89 Fed. Reg. 35934 (May 2, 2024).
[2] Brookings, Drug Shortages: A Guide to Policy Solutions (Mar. 13, 2024), *available at* https://www.brookings.edu/articles/drug-shortages-a-guide-to-policy-solutions/.
[3] *Id.*
[4] For example, drug shortages within the hospital setting are often for GSIs. A 2016 U.S. Government Accountability Office (GAO) report found that shortages for GSIs are typically caused by manufacturers slowing or stopping production to address reliability concerns. Issues with manufacturing still contribute to GSI shortages today. For example, Accord Pharmaceuticals contributed to a shortage of two generic sterile

we applaud the idea of achieving help for small, independent hospitals battling drug shortages. We offer the following recommendations herein to help ensure CMS' proposal aligns with current strategies that distributors use to address supply chain disruptions:

1. **CMS should focus the proposal to include drugs that are critical in the hospital setting.**
2. **CMS should consider supplier diversification in the proposal.**
3. **CMS should consider a phased approach to payments under the proposal.**
4. **CMS should assess whether there will be meaningful adoption of the proposal from small, independent hospitals.**
5. **CMS should prioritize equity in this proposal so that no setting is advantaged over another.**
6. **CMS should consider support for current stockpiling strategies.**

Beyond our recommendations, we stand ready to advance approaches such as those outlined in HDA's guiding principles and policy agenda, where supply chain stakeholders and the government can work together to address drug shortages.[5]

I. Distributors help address drug shortage concerns.

Distributors help address drug shortage concerns in a variety of ways, including:

- ***Inventory Management and Investments***: Distributors employ systems that allow providers to place orders that arrive shortly before redelivery to providers/patients. By doing so, distributors help to reduce the need for large amounts of storage space, while reducing inventory carrying costs as well as security and diversion risks of holding expensive, high-risk products. Distributors use these systems to ensure efficiency, reduce costs, and streamline delivery of products. Inventory management systems include just-in-time delivery, which is essential for healthcare facilities that do not have the physical capabilities to hold large amounts of product and protects them from holding expensive products or products at high risk of diversion.

- ***Product Alternatives*:** When possible, distributors leverage national and regional networks to offer alternative medications to maintain patient care, when appropriate.[6] This is a capability that distributors can provide because of their widespread access and connections to the distribution network.

- ***Demand Forecasting*:** By utilizing sophisticated inventory forecasting tools. distributors work to forecast demand and potential disruptions caused by events like seasonal flu outbreaks to inform anticipatory purchasing decisions. Distributors share these forecasts with manufacturers, enabling them to predict production needs.

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injectables—cisplatin and carboplatin—due to an import ban following an FDA inspection revealing violations of cGMPs and data integrity concerns. IQVIA, Drug Shortages in the U.S. 2023 (Nov. 15, 2023), *available at* https://www.iqvia.com/form-pages/institute-gated?redirectUrl=%2f-%2fmedia%2fiqvia%2fpdfs%2finstitute-reports%2fdrug-shortages-in-the-us-2023%2fdrug-shortages-in-the-us-2023.pdf&title=Drug+Shortages+in+the+US+2023; U.S. Government Accountability Office, Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge (published 2016), *available at* https://www.gao.gov/assets/gao-16-595.pdf.

[5] Healthcare Distribution Alliance, HDA Policy Platform on Drug Shortages, *available at* https://www.hda.org/drug-shortages/.

- ***Equitable Allocation***: To ensure that medicine is available to as many customers as possible, distributors account for available supply and customer needs when allocating disrupted drugs. Equitable allocation programs help provide access to as many customers as possible when supply is limited.

In addition, distributors collaborate with customers to manage and maintain buffer inventory to mitigate shortages to contribute to a resilient supply chain. To that end, distributors are uniquely positioned to be a key partner in any buffer stock proposal.

II. Recommendations to help ensure the proposal aligns with current strategies that distributors use to address supply chain disruptions.

Should CMS move forward with the proposal, we ask the agency to consider our recommendations to address the sustainability of the proposal and help ensure that the proposal aligns with current strategies that distributors use to address supply chain disruptions.

Recommendation 1: CMS should focus the proposal to include drugs that are critical in the hospital setting.

Unlike last year's buffer stock proposal,[7] CMS explains that this proposal narrows the scope of eligible participants to small, independent hospitals, many of which are rural, that may lack the resources available to larger hospitals and hospital chains to establish and maintain buffer stocks of essential medicines for use in the event of drug shortages.[8] CMS further explains that because small and independent hospitals often lack resources in-house to maintain buffer stock programs, it anticipates that most hospitals that elect to establish and maintain buffer stocks under the proposal will do so through contractual arrangements with pharmaceutical intermediaries, manufacturers, and distributors.[9] CMS codifies by reference the Advanced Regenerative Manufacturing Institute (ARMI) List of essential medicines as its source list for products under the proposal.[10]

HDA appreciates that CMS has narrowed the scope of the facilities that may participate in the buffer stock proposal. We further suggest that CMS focus the proposal to include drugs that are critical in the hospital setting. Thus, we urge CMS to reconsider adopting the ARMI List of essential medicines as its source list for products under the proposal because the list is not tailored to patient care in a hospital setting. Instead, we urge CMS to consider adopting an adjusted list of inventories required under the proposal that more appropriately captures products in hospitals, which could in turn reduce the potential cost of the program, as well as address unnecessary burden on hospitals and the entities they work with to maintain a buffer stock.

Should the ARMI list be the basis of the proposal, we ask that CMS ensure that the ARMI List is harmonized with FDA's own drug shortages list, which is the list that distributors commonly use. We also urge CMS to identify a process by which the list should be updated to reflect drugs in the hospital setting. Such a process is critical for hospitals to determine which products on the ARMI List would be included in their own stockpile strategy. As CMS anticipates distributors would be a part of the buffer stock strategy, each distributor will have to maintain a discrete buffer stock for each hospital. Distributors need an updated list to provide the needed flexibility for distributors to rotate products as

[7] 88 Fed. Reg. 49552 (July 31, 2023).
[8] 89 Fed. Reg. 35934, 36232.
[9] *Id.* at 35236.
[10] *Id.*

part of many inventory management programs as well as anticipate or forecast demand surges in other local or national locations.

Recommendation 2: CMS should consider supplier diversification in the proposal.

CMS states that it is necessary to support practices that can mitigate the impact of pharmaceutical shortages of essential medicines and promote resiliency to safeguard and improve the care hospitals are able to provide to patients. In doing so, CMS states that the proposal seeks to sustain sources of domestically sourced medical supplies, which can help support continued availability in the event of public health emergencies and other disruptions."[11]

HDA supports federal investments in domestic manufacturing that create supply chain redundancies, decrease the risk of a drug shortage, and support national security. HDA also acknowledges the importance of supplier diversification, including from sources outside of the country. Supplier diversification plays an important role in addressing drug shortages because distributors seek to have their customer bases supported by multiple manufacturers (sometimes referred to as supplier redundancy) to prevent overreliance on a single source of supply. This strategy helps both the supplier and downstream customer because the manufacturer can plan for production while the customer is supported by multiple manufacturers that can act as a buffer to minimize disruptions.

It is HDA's understanding that there may not be enough domestic production capabilities to meet the needs of hospitals. To that end, CMS should consider balancing domestically manufactured drugs under the proposal with current supplier diversification, as failure to do so could and increase costs of the program (and possibly program participation). We urge CMS (and the federal government more broadly) to continue to prioritize federal investments in domestic manufacturing that can help create supply chain redundancies, decrease the risk of a drug shortage, and support national security.[12]

Recommendation 3: CMS should support a phased approach to payments under the proposal.

In the proposal, CMS requests comments on whether this proposed policy should be phased in by the size of the buffer stock to address concerns about infrastructure investments that may be needed to store and maintain the supply.[13]

From the distribution perspective, the proposal could include expanding warehouse capacities and managing product expiries and replenishment of expanded inventories. While distributors are uniquely positioned to assist with this proposal, CMS should consider a phased approach for implementation to account for any operational changes. We suggest the phased approach be at least one year in length.

Recommendation 4: CMS should assess whether there will be meaningful adoption of the proposal from small and independent hospitals.

CMS draws on other payment adjustment proposals to support the buffer stock proposal. Notably, CMS states that the buffer stock proposal's payment adjustment concept is consistent with CMS'

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[11] *Id.* at 36232.
[12] Healthcare Distribution Alliance. HDA Policy Agenda on Drug Shortages. Published 2024. https://www.hda.org/getmedia/1457f7bf-d36f-4f28-8457-c06007a6ec53/HDA-Policy-Agenda-on-Drug-Shortages.pdf.
[13] 89 Fed. Reg. 35934, 36236.

current policy for domestic National Institute for Occupational Safety and Health (NIOSH) approved surgical N95 respirators.[14]

While HDA understands that CMS can build support for this proposal from other similar payment adjustment policies, we urge CMS to assess whether small and independent hospitals have meaningfully adopted CMS' payment adjustment for surgical N95 respirators. This data point can inform CMS on whether this buffer stock proposal will likewise be adopted by small, independent hospitals.

Recommendation 5: CMS should prioritize equity in this proposal so that no setting is advantaged over another.

CMS considers that in estimating the amount of a buffer stock needed for each essential medicine, the hospital should consider that the amount needed to maintain a buffer stock could vary month to month and throughout the applicable months of the cost reporting period.[15]

We appreciate CMS' acknowledgement that buffer stock needs vary from hospital to hospital. We also acknowledge that there will be seasonal surges in product needs (e.g., cold and flu season) While rural hospitals are important healthcare providers, we urge CMS to also consider the impact a buffer stock proposal could have on other setting, like physician practices and pharmacies, who are not eligible for the payment adjustment under the proposal. We are concerned that buffer stock programs can encourage "hoarding" behavior, wherein one setting is disadvantaged over another, particularly when one setting is being incentivized to build inventories and the others are trying to minimize costs by holding minimal inventory. We urge CMS to outline how incentive payments are managed to ensure that hoarding behavior is not rewarded under the program.

Further, we underscore the need for CMS to support an equitable approach to the proposal that would enable facilities to adjust their volume based on projected need, location, and relationship with distributors. One way CMS could do this is to incentivize the use of regional stockpiles, like the Strategic National Stockpile (SNS) because it would allow facilities (including physician practices) to drawdown products on an as needed basis.

Additionally, HDA recommends that the proposal prioritize sharing information with federal, regional, and state stockpiles (as appropriate) because this bidirectional data sharing will provide greater transparency into potential hoarding behavior.

Recommendation 6: CMS should consider support for current stockpiling strategies.

HDA supports federal investments in public-private partnerships to strategically increase the inventory of medicines. These investments can be used as a tool to increase the supply of products on hand, specifically for products that would need to be used during medical surges, such as the seasonal cold and flu season. Strategically increasing inventory through vendor managed inventory (VMI) contracts can help mitigate the impact of drug shortages, in addition to helping stabilize prices and addressing national security issues. For instance, the Administration for Strategic Preparedness and Response (ASPR) Regional Disaster Health Response System (RDHRS) offered pilots that incorporated the concept of regional stockpiles.

[14] 87 Fed. Reg. 72037 (Nov. 23, 2022).
[15] 89 Fed. Reg. 35934, 36235.

We encourage CMS to consider building on this program to consider a regional stockpile system for hospitals, which would streamline product rotation and returns, minimize administrative burden, ensure resilience in available supply for the region, and provide the necessary flexibility to move the product across the region based on need.

Conclusion

Thank you for the opportunity to provide comments on this important proposal. Recognizing the pivotal role that distributors play in mitigating drug shortages, HDA looks forward to continued collaboration with CMS to build and support a more resilient pharmaceutical supply chain. If you have any questions, please contact me at kshankle@hda.org.

Sincerely,

/s/ Kala Shankle

Kala Shankle
Vice President, Regulatory Affairs