Healthcare Distribution Alliance

HEALTH DELIVERED

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Elise Barringer
Advisory Panel on Hospital Outpatient Payment (HOP Panel)
Centers for Medicare & Medicaid Services, Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: C.Y. 2024 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (July 31, 2023) Docket No. CMS-1786-P

Dear Ms. Barringer,

We appreciate the opportunity to comment on the C.Y. 2024 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (July 31, 2023), Docket No. CMS-1786-P. We appreciate the role of the Centers for Medicare & Medicaid Services (CMS) to impact and identify policy solutions to ensure continued access to medicines.

The Healthcare Distribution Alliance (HDA) is the national organization representing primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. HDA advocates on behalf of pharmaceutical wholesalers and distributors, leads the sector on relevant policy, and fosters relationships across partner organizations. Healthcare distributors ensure the safe, efficient, and reliable delivery of medications, vaccines, and other critical medical products. HDA's members find the safest and most efficient ways to get medical products to providers and patients at the place and time they are needed.

Drug shortages, and the impact of drug shortages on patients, has remained in focus since 2011, when more than 250 new drugs were in shortage.[1] Since that time, the public health implications of drug shortages have remained clear. Distributors recognize the challenges drug shortages may pose to patients and healthcare systems. Distributors leverage their capabilities to help mitigate drug shortages daily and manage them equitably when they occur. While there is appreciation of the public health impact of drug shortages, distributors are aware of the strain chronic drug shortages pose on hospitals and health systems. We welcome market-based solutions as a sustainable option to help mitigate shortages.

The drivers of drug shortages are also complex and highly nuanced. From the pharmaceutical distribution perspective, the factors that contribute to each drug shortage are unique, often with multiple drivers at play.

[1] U.S. Food and Drug Administration. "Tenth Annual Report on Drug Shortages for Calendar Year 2022." https://www.fda.gov/media/169302/download.

Chronic drug shortages, such as generic sterile injectable shortages, impact hospitals because generic sterile injectables are used for patient care in emergency rooms, intensive care units (ICUs), cancer clinics, and outpatient elective surgery departments.[2] Nearly every patient in a hospital setting is treated with a generic sterile injectable drug.[3] Generic sterile injectables have been in shortage due to quality issues and the lack of investment in robust manufacturing processes to mitigate contamination issues that may arise.[4] HDA and its members ask CMS to consider modifying the Proposed Rule to focus on frequent products in shortage, such as generic sterile injectables, and other products that are the most likely to be in shortage and will most likely impact patient care within a hospital setting.

In order to think about drug shortages based on their primary drivers, HDA and its members categorize drug shortages as *supply-driven* or *demand-driven* shortages.[5] Supply-driven shortages are defined as a drug shortage that is caused by disruptions to manufacturing or raw materials supply availability.[6] Demand-driven shortages are caused by medical surges that create a sudden uptick in orders.[7] The drivers of supply-driven shortages are upstream and are often rooted in manufacturing issues or market access challenges. The drivers of demand-driven shortages can be categorized by sudden medical surge. Regardless of the driver, drug shortages occur because there is a lack of supply to meet the current demand. Because of the complexities and nuances of drug shortages and their root causes, there is no single solution to solving shortages.

Under the Proposed Rule, to receive reimbursement from Medicare Part A, hospitals must establish, purchase, and maintain a buffer stock of 86 essential medicines. These essential medicines were previously identified in a report from the Assistant Secretary for Preparedness and Response (ASPR) as important for acute care, with no comparable alternatives.[8] Hospitals may partner with supply chain stakeholders, such as distributors, to establish and maintain this buffer stock. Hospitals will be reimbursed through Medicare Part A biweekly, and the hospital will pay the distributor directly if they choose to partner with one. HDA recognizes this Proposed Rule as a potential strategy to increase the amount of inventory held by hospitals through a Vendor Managed Inventory (VMI) solution. We offer these considerations as the Proposed Rule is revised.

HDA and its members encourage CMS to consider key factors of this proposed program based on the feasibility of implementation as well as through an equity lens. **As written, the process of establishing and maintaining a three-month dedicated buffer stock could cause shortages in the near term. The process of establishing and maintaining a buffer stock will also be challenging for many hospitals that are already facing financial difficulties.**

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[2] The Hamilton Project. Wosinska, Marta E. Frank, Richard G. "Federal Policies to Address President Generic Drug Shortages." Published June 2023. https://www.brookings.edu/wp-content/uploads/2023/06/20230621_ES_THP_GSI_Report_Final.pdf.
[3] Ibid.
[4] Healthcare Distribution Alliance. "HDA RFI Submission Drug Shortages." Published July 2023. https://www.hda.org/getmedia/cc3658b0-cebe-47cd-a944-0af2504ece9a/HDA-RFI-Submission-Drug-Shortages.pdf.
[5] Healthcare Distribution Alliance. "HDA RFI Submission Drug Shortages." Published July 2023. https://www.hda.org/getmedia/cc3658b0-cebe-47cd-a944-0af2504ece9a/HDA-RFI-Submission-Drug-Shortages.pdf.
[6] Ibid.
[7] Ibid.
[8] Nexight Group. "Essential Medicines Supply Chain and Manufacturing Resilience Assessment." Published May 2022. https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf.

The Proposed Rule offers stockpiling as a strategy to manage drug shortages. HDA and its members view stockpiling as an important action to build resilience in the supply chain. Currently, distributors partner to support stockpile expansion efforts through providing VMI in both the Strategic National Stockpile (SNS) and state stockpiles.[9] Using VMI for stockpiles significantly reduces the risk of products expiring because distributors rotate and cycle commercial inventory within the stockpile through commercial channels.

Based on the considerations necessary for the Proposed Rule, HDA and its members respectfully ask CMS to consider the following questions regarding the overall scope of the program.

1. How does this program impact the resilience of the overall hospital system long-term?
2. Will the program be assessed on an ongoing basis to determine if it is accomplishing the intended goal(s)?
3. How will the drawdown of specific products in the stockpile be managed? Is a refresh of those products (at some time certain) required for compliance with the program?
4. Will compliance with this program be included in other CMS hospital inspections?

HDA and its members respectfully ask CMS to consider these questions from the distribution industry regarding the scope and implementation of the Proposed Rule. We have also enclosed our considerations regarding equity, logistics, and the feasibility of the Proposed Rule.

Implementation and Supply Chain Considerations

The distribution industry has questions regarding the implementation and maintenance of the program, once established. The new program should consider supplier diversification and the feasibility of stocking products that are in or at risk of shortage. In order to build a three-month buffer stock for hospitals, we recommend a detailed phased approach to successfully build these stockpiles over a stated time duration (1 – 2 years, for example). **Without a phased approach, there would likely be a significant drawdown of product from the supply chain to build these stockpiles, which is likely to cause shortages.**

When distributors partner with suppliers, they focus on supplier diversification and creating redundancies to ensure a reliable supply of products to meet customers' needs. While distributors recognize the intention of preferencing domestically manufactured drugs is to create a more robust domestic supply chain, distributors have concerns. The distribution industry is concerned that preferencing domestically manufactured drugs through higher Medicare Part A reimbursement will not prioritize supplier diversification. There is a question of feasibility because the 86 drugs identified by ASPR may not be the medicines most likely to go into shortage or affect patient care in a hospital setting. The list of the 86 drugs was captured by ASPR based on historical data in a 2022 analysis. The Proposed Rule does not offer a plan to update the list to reflect current drugs in shortage or near shortage. Distributors understand that it is challenging to predict product availability and what drugs will be in shortage. Without an updated list of drugs at risk of shortage, it may not be the best use of distributor capabilities to stockpile on behalf of individual hospitals because the drugs being stockpiled may no longer be at risk of a shortage or important to patient care in a hospital setting.

Stockpiling strategies can benefit regional stakeholders, given the need to move medical products across hospitals and other facilities based on need. As currently written, the Proposed Rule does not

[9] Healthcare Distribution Alliance. "HDA RFI Submission Drug Shortages." Published July 2023. https://www.hda.org/getmedia/cc3658b0-cebe-47cd-a944-0af2504ece9a/HDA-RFI-Submission-Drug-Shortages.pdf.

offer clarity around the flexibility of the stockpile. There is concern that the hospital-level stockpiles would prevent distributors from being able to shift product from one hospital to another based on need and add complexity to the distribution model as it relates to managing stock rotation and returns. This flexibility is an important component of a stockpiling strategy, considering that medical surge could occur in hospitals which may deplete their own stock.

While hospital-level stockpiling offers a simpler reimbursement route through Part A, HDA and its members respectfully request CMS to consider a regional stockpiling strategy. The ASPR Regional Disaster Health Response System (RDHRS) offered pilots that incorporated the concept of regional stockpiles. We encourage CMS to consider building on this program to consider a regional stockpile system for hospitals, which would streamline product rotation and returns, ensure resilience in available supply for the region and provide the necessary flexibility to move the product across the region based on need.

Implementation Questions

1. Would CMS consider a pilot program or demonstration project to be implemented in advance of a full launch?
2. Will the rule, once established, include guidance on a phased approach to build the stockpiles?
    a. How can buffer stockpiles be established with a phased-in approach, to avoid creating drug shortages driven by a rapid uptick in orders to fill the buffer stock? How will hospital systems with multiple hospitals be expected to manage their buffer stock?
3. Will buffer stock be able to be used for any hospital within a hospital system, or is it dedicated to a specific hospital?
4. Are hospitals expected to keep separate inventory for inpatient and outpatient drugs?
    a. If a hospital works with a distributor, is the distributor expected to manage the inpatient and outpatient inventory separately?

Logistical Considerations

As currently written, the Proposed Rule does not require hospitals who choose to establish and maintain buffer stock to share information with state stockpiles (if applicable) or the SNS. **That means a hospital may choose not to disclose what is in its buffer stock and the federal agencies may not have visibility on the products held in stockpile.** This has implications for a demand-driven event where the SNS may need to release product. **We recommend a modification of the Proposed Rule to include a requirement to share information with the federal, regional, and state stockpiles (as appropriate).** Without this, the lack of coordination will make it highly challenging to coordinate stockpile strategies and understand local medical countermeasure needs during an event.

The Proposed Rule, as written, could pose many logistical challenges for hospitals and their distributor partners. Distributors have the ability and capacity to partner with hospitals to establish and manage buffer stock. Logistically, while distributor capabilities allow them to physically manage 3-months' worth of buffer stock for our nation's 6,129 hospitals, the ability to move product across customers and regions based on need could be hindered by this program.[10] It is important to note that this program would not obviate the need for other tools distributors utilize to mitigate and manage

[10] American Hospital Association. "Fast Facts on U.S. Hospitals, 2023." Published 2023. https://www.aha.org/system/files/media/file/2023/05/Fast-Facts-on-US-Hospitals-2023.pdf.

shortages.[11] While possible, there might be challenges associated with housing and managing hospital-specific stockpiles, especially during disruptions such as drug shortages.

Logistical Questions

1. Will product be expected to rotate within a stockpile so the product does not expire?
2. Is a buffer stock for all 86 essential medicines the required strategy, or are hospitals permitted to build the stockpile based on the products they view as priority for their hospital/health system?
3. If a hospital works with a distributor, does the distributor have the ability to rotate product (based on need) across other hospital systems in their Vendor Managed Inventory (VMI)?
4. Will a process be established to review and refresh the essential medicines list on a timely basis?

Equity Considerations

As currently written, the Proposed Rule does not lay out an equity lens in the current strategy to build and maintain the stockpile program equitably. Recognizing that there are existing equity concerns in healthcare delivery and access – most notable in the challenges of rural hospitals – it is important to ensure that this Proposed Rule would not exacerbate these inequities.

Distributors believe that healthcare equity can be achieved through intentional policies and practices that ensure the attainment of full health potential, regardless of socioeconomic or medical status.[12] The focus on healthcare equity for distributors shifts the focus towards the role of healthcare facilities and organizations, including the role of the supply chain in addressing equity. In the case of drug shortages, distributors incorporate a fair-share allocation process to ensure that available medical product is distributed across their customer base according to need (not purchasing ability). This practice is critical to ensuring that limited supply can be distributed equitably. As currently described, the Proposed Rule does not include provisions for moving product across customer bases in times of shortage, a practice which could make it challenging to allocate product to hospitals in accordance with their legitimate need for product.

Many hospitals may not have the financial ability to purchase a 3-month buffer stock of the 86 essential medicines required for Medicare Part A reimbursement by the Proposed Rule. The equity concerns are even more pronounced for hospitals already financially struggling, as more than half of U.S. hospitals were projected to have negative margins through the end of 2022.[13] Ensuring that there is a phased-in or opt-in plan for hospitals with limited resources (funding and space) is vital to implementing such a program. Without such a process, the hospitals that are without financial resources to begin to execute contracts and start to build stockpiles will be left behind.

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[11] Healthcare Distribution Alliance. "Drug and Medical Product Availability: Distributors Promote a Resilient Supply Chain." Published 2023. https://www.hda.org/getmedia/45f48c39-69e6-4ff8-8919-af1c4cfb7432/Drug-and-Medical-Supply-Shortages.pdf.

[12] Healthcare Distribution Alliance. "Distributors and Healthcare Equity: An Overview." Published 2023. https://www.hda.org/getmedia/2ce1b335-1211-43c3-9a38-a7e597d0afc8/Distributors-and-Healthcare-Equity.pdf.

[13] Kaufman, Hall. "The Current State of Hospital Finances: Fall 2022 Update." Published September 15, 2022. https://www.aha.org/system/files/media/file/2022/09/The-Current-State-of-Hospital-Finances-Fall-2022-Update-KaufmanHall.pdf.

Current Stockpiling Legislative Proposals

It is important to note that this Proposed Rule is among several proposals to stockpile or increase buffer stock in the healthcare supply chain. The 118th Congress is reviewing legislative proposals which would, if signed into law, come into effect at the same time as the Proposed Rule. The stockpiling proposals include: H.R. 405, the Essential Medicines Strategic Stockpile Act (EMSSA) of 2023, the VMI strategy within the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics Act (PREVENT Act), the state stockpile pilot proposal within the Senate Pandemic and All-Hazards Preparedness Act (PAHPA) reauthorization, and S. 2510, the (Rolling Active Pharmaceutical Ingredient and Drug) RAPID Reserve Act.

EMSSA is bipartisan legislation that seeks to amend the Public Health Service Act to establish a pilot program that creates a six-month stockpile of generic drugs at risk of shortage. Under this proposal, the HHS secretary will determine the 50 generic drugs chosen to be in the stockpile. HDA and its members recommend that H.R. 405 be included in the PAHPA reauthorization legislation.

The bipartisan legislation PREVENT, passed as a part of the Omnibus Package of 2022, expanded the authorization of the SNS VMI, warm base capacity, and the Public Health Emergency Fund (PHEF) for the initial deployment and distribution of SNS products. The bipartisan proposal within the Senate HELP reauthorization of PAHPA continues the pilot program that supports state medical stockpiles. HDA and its members support funding for state stockpiles because each state and region may face different public health threats due to geographic area. As state stockpiles are created, distributors encourage state stockpiles to have IT linkages and routine coordination with the SNS.

The RAPID Reserve Act, a bipartisan bill seeks to require the U.S. Department of Health and Human Services (HHS) to award generic manufacturers in the U.S. or Organization for Economic Cooperation and Development (OECD) member countries with contracts to keep reserves of active pharmaceutical ingredients (API) and finished products on hand. The RAPID Reserve Act will prioritize U.S. manufacturers for federal contracts. HDA and its members support the bipartisan legislation and believe it will increase capacity for generic drugs in the U.S. through VMI.

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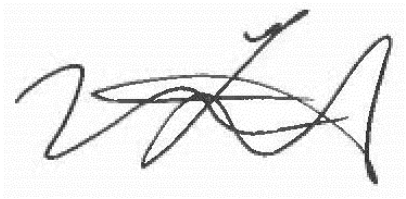
Given the considerations shared by the distribution industry, HDA and its members respectfully urge CMS to modify the Proposed Rule, prior to finalization. While it is our hope that the revisions will incorporate factors shared in this letter, we would welcome the opportunity to share additional perspectives in an in-person meeting. Recognizing the impact of this Proposed Rule on multiple stakeholders, we would be happy to help convene a cross-stakeholder meeting to discuss the details of the Proposed Rule.

If you have any questions or want additional information, please contact Dr. Nicolette Louissaint by email at nlouissaint@hda.org.

Sincerely,



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