

Centers for Medicare and Medicaid Services

CMS-1786-P

September 11, 2023

To whom it may concern,

The Robert J. Margolis, MD, Center for Health Policy at Duke University (“Duke-Margolis”) appreciates this opportunity to provide comments and recommendations regarding provision “XXII. Request for Public Comments on Potential Payment Under the IPPS and OPSS for Establishing and Maintaining Access to Essential Medicines” of this proposed rule.

Duke-Margolis has conducted years of research and stakeholder engagement aimed at promoting drug supply chain resilience and preventing drug shortages, most recently including the launch of the new [Duke-Margolis Drug Supply Chain Resilience and Advanced Manufacturing Consortium](#). The recommendations herein do not necessarily represent the views of any Consortium Members and are not intended to limit the ability of Consortium members to provide their own comments on behalf of their independent organizations, but are informed by Duke-Margolis’ work with Consortium Members. Please note that in addition to the recommendations put forth in this comment, Duke-Margolis also recently published a white paper, [Advancing Federal Coordination to Address Drug Shortages](#), with a broader set of recommendations for administrative and legislative action on drug shortages. The white paper proposes the establishment of a Prevent Drug Shortages Initiative to coordinate ongoing efforts across the federal government, including within CMS, to more effectively address pressing drug shortage issues.

Comment on Buffer Stock Proposal

Although the buffer stock proposal could potentially reduce the likelihood of drug shortages in certain cases, the proposal may also incur significant costs and administrative burdens, both for CMS and for health systems, without addressing the primary root causes of chronic drug shortages. In some cases, for example for drugs currently in shortage, the proposed payment mechanism could have the unintended consequence of contributing to short-term demand-driven shortages of essential medicines. Therefore, while we appreciate CMS’ appropriate focus on preventing drug shortages and some potential benefits of this proposal, other steps may be more cost-effective and more directly address the root causes of drug shortages.

The leading cause of drug shortages is manufacturing quality issues. Drug payment policies and limited transparency into manufacturers’ supply chains mean purchasers choose manufacturers largely based on lowest price, which creates adverse market incentives for manufacturers to keep costs down even at the expense of needed investments in supply chain reliability. Holding a higher buffer stock of inventory will not change the U.S. generic drug supply’s current reliance on manufacturing facilities that are not using modernized processes and do not consistently employ strong quality management maturity practices, nor will it provide adequate incentive for deployment of adequate capacity, redundancy, flexibility, and strong risk mitigation strategies to prevent drug shortages.

In the future, CMS should develop a voluntary payment program that provides additional support to drug purchasers based on the reliability of their drug suppliers, e.g., through offsetting incremental costs

associated with implementing a committed purchase contract for medicines at high risk of shortage with a supplier that demonstrates use of reliable manufacturing and supply chain practices and/or faces substantial penalties for failing to provide a consistent and reliable supply. Such a program would be targeted toward the root causes of drug shortages. As we described in our recent [white paper](#), we recommend CMS partner with FDA and other relevant federal agencies to advance a combination of payment reforms and metrics to increase supply chain reliability to reduce drug shortages.

With our concerns regarding cost, administrative burden, and unintended consequences associated with this rule stated, we also note a few key points for CMS' consideration should the buffer stock proposed policy proceed:

- **Storing buffer stock inventory at the health system level is often less efficient than storing at wholesalers/distributors or manufacturers.** The latter can create economies of scale by concentrating storage/distribution in large distribution centers, enable a more nimble supply chain that can respond to provider needs and changes in demand more quickly, and avoid the higher obsolescence costs that will occur if inventory is stored at health systems.
- **Buffer stock inventory payments should not be made for drugs when they are in shortage.** Hospitals should not be encouraged to keep a significant stock of drugs while they are in shortage, as this would exacerbate the effects of the shortage for other institutions and sites of care. Payments for buffer stock inventory could be discontinued upon a drug being added to the FDA Drug Shortage List, though stopping and starting payments could in itself create administrative burden and potentially unintended consequences.
- **Tracking actual costs could be burdensome and incentivize higher costs, but effective methods exist to generate reasonable estimates or averages.** Tracking and reimbursing health systems for actual costs incurred for the buffer stock would likely be very burdensome, inaccurate, and encourage inefficient purchasing. As with other CMS payment programs, any buffer stock payments should be based on reasonable estimated or average inventory carrying costs. Some of the most significant inventory carrying costs are capital costs (opportunity cost of money devoted to inventory that could have been invested elsewhere), warehousing costs, obsolescence costs when products expire, etc. Some relevant research on inventory carrying costs is below.
 - [Lambert and LaLonde](#) – 14-43% of inventory value per year
 - [Monczka, Handfield, Giunipero, and Patterson](#) – 15-25% of inventory value per year
 - [Logistical Management, by Bowersox and Closs](#), provides another helpful breakdown of inventory holding costs featuring averages and ranges for each line item and the total estimate:
 - Capital Cost Average 15% (Range 8-40%)
 - Taxes 1% (0.5-2%)
 - Insurance 0.05% (0-2%)
 - Obsolescence 1.2% (0.5-2%)
 - Storage 2% (0-4%)
 - **Total 19.25% (Range 9-50%)**

Inventory carrying costs are usually very dependent on production costs. For example, drugs that are more costly to produce have higher capital costs and obsolescence costs. As a result, CMS may need to estimate the production costs of the buffer inventory. An inventory carrying

cost assumption derived from the above references and other sources could then be applied to the estimated production costs of the buffer inventory to arrive at a reasonable payment amount. When manufacturers hold an inventory buffer, their inventory carrying costs are based on the drugs' cost of production, not the average sales price (ASP), so ASP may not by itself be an appropriate metric to use to value buffer inventory.

In summary, potential components of a buffer stock inventory payment calculation could include 1) an inventory carrying cost assumption, 2) the annual usage of a drug reported by a health system, 3) number of months of inventory in the buffer stock, and 4) ASP multiplied by a production cost % assumption.

- **These proposed payments, if implemented, would be most effective if accompanied by shelf life extension efforts.** Holding an adequate buffer stock is more difficult for products with shorter expiration dating. For example, after considering timing from manufacturing to quality control release, distribution timelines, normal variability in supply and demand, and common business norms that involve quarantining product with less than 12 months before expiration for destruction, a drug with 18 months shelf life often has a window of less than 3 months available for holding a buffer stock. CMS could consider how to reduce obsolescence costs and encourage manufacturers to run stability studies to seek longer expiration dating.

Again, we thank CMS for its focus on preventing drug shortages, and look forward to supporting further payment policy proposals to support a reliable drug supply for U.S. hospitals and health systems.

Sincerely,

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