

## Managing Drug Shortages

Drug shortages are a long-standing and persistent problem in healthcare that can disrupt operations and work processes, cause patient harm, and have serious financial consequences for healthcare organizations. An inadequate drug supply can result in the need to delay care, cancel treatments, ration medications, or find alternative (possibly suboptimal) treatments.

Drug shortages also increase the risk of medication errors as a result of human and systems factors. “Medication errors are more likely to occur (1) when a pharmacy alters how a product is ordered, prepared, or dispensed or (2) when prescribing practices change to less familiar alternative agents, especially agents that are less efficacious, have a worse adverse-effect profile, or require an unusual or difficult dosing regimen.”<sup>1</sup>

Addressing drug shortages is complex because the supply chain itself is complex; complications can occur at any stage — from raw material production to wholesale distribution to pharmacy purchasing. Many proposed solutions are beyond the control of healthcare organizations and require broader intervention from the pharmaceutical industry, government agencies, policymakers, etc.

However, healthcare organizations can proactively prepare for drug shortages and implement strategies to help minimize their impact on staff and patients. The following tips are not all-inclusive, but they offer general guidance and recommendations to help healthcare organizations develop policies for addressing drug shortages while safeguarding patients and mitigating risks.<sup>2</sup>

1

Establish a comprehensive written plan for managing drug shortages, including convening interdisciplinary teams to help develop guidance, determine roles and responsibilities, oversee drug- and pharmacy-related processes, facilitate change management, and make ethical decisions about resource allocation.

2

As part of planning for drug shortages, make sure appropriate staff members are assigned key responsibilities, such as monitoring for shortages; purchasing alternative medications; modifying storage, preparation, and dispensing procedures; making rationing/conservation decisions; incorporating or changing technology, and communicating effectively with all stakeholders.

3

Educate providers and staff members about drug shortages, their potential consequences, and strategies to manage shortages and mitigate risks. These strategies might include extending expiry dates, using products with minor defects (after risk evaluation), reducing unnecessary prescribing, decreasing drug waste, and proactively identifying potential alternative therapies.

4

Develop a standardized process for approving alternative drugs and therapies, and make sure the process is devised with input from medical specialties, nursing, and pharmacy. The Institute for Safe Medication Practices also recommends developing an expedited approval process to use in more urgent situations, but cautions that organizations keep in mind [important safety considerations](#).

5

Develop an ethical framework to help guide clinicians in difficult decision-making during drug shortages, such as rationing and choosing drug alternatives. Ensure appropriate support and resources are in place to provide consultation and help manage clinician distress or anxiety related to drug shortage decisions.

6

Be aware that different types of drug shortages might require different approaches, processes, and ethical frameworks. Revisit policies and procedures as necessary to optimize organizational response.

7

When drug shortages are identified, conduct thorough assessments to determine key details and analyze the clinical and financial impact. Key details to assess include current inventory, historical usage, cause of the shortage, estimated duration of the shortage, affected patient populations, potential alternative sources and therapies, and so on.

8

Following assessments and impact analyses, develop a final plan that delineates the selected approach and key strategies for managing each drug shortage. The plan should give consideration to timing of activities and incorporate details related to updating technology systems, modifying workflow patterns, and making necessary changes to medication inventories.

9

Develop guidance related to in-house pharmacy compounding as well as obtaining products from external compounding pharmacies or other sources. Ensure that [due diligence criteria](#) are in place to evaluate external pharmacies.

10

Develop a diversified strategy for efficiently communicating about potential and confirmed drug shortages. Consider how best to communicate with leadership, clinicians, pharmacy staff, patients and families, the media, and others.

11

Ensure an adequate system is in place for staff members to report medication errors, adverse events, and near misses. When medication mishaps occur as a result of drug shortages, staff should make sure to include those details in documentation.

12

Stay current on resources, tools, and guidance from the government and professional associations on managing current drug shortages and predicting future shortages.

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## Resource

For more detailed guidance and advice related to managing drug shortages, see MedPro's [Risk Resources: Drug Shortages](#).

## Endnotes

<sup>1</sup> Fox, E. R., & McLaughlin, M. M. (2018). ASHP guidelines on managing drug product shortages. *American Journal of Health-System Pharmacy*, 75(21), 1742–1750. doi: <https://doi.org/10.2146/ajhp180441>

<sup>2</sup> The risk tips in this publication are adapted from the following resources: Fox, et al., ASHP guidelines on managing drug product shortages; Shukar, S., Zahoor, F., Hayat, K., Saeed, A., Gillani, A. H., Omer, S., Hu, S., Babar, Z. U., Fang, Y., & Yang, C. (2021). Drug shortage: Causes, impact, and mitigation strategies. *Frontiers in Pharmacology*, 12, 693426. doi: <https://doi.org/10.3389/fphar.2021.693426>; Institute for Safe Medication Practices. (2010, October 7). *Weathering the storm: Managing the drug shortage crisis*. Retrieved from [www.ismp.org/resources/weathering-storm-managing-drug-shortage-crisis](http://www.ismp.org/resources/weathering-storm-managing-drug-shortage-crisis); Cierniak, K. H., Gaunt, M. J., & Grissinger, M. (2019). Drug shortages: Shortchanging quality and safe patient care. *Pennsylvania Patient Safety Advisory*, 16(1). Retrieved from [https://patientsafety.pa.gov/ADVISORIES/Pages/201903\\_DrugShortages.aspx](https://patientsafety.pa.gov/ADVISORIES/Pages/201903_DrugShortages.aspx)

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