# Crisis Standards of Care Considerations: Pharmaceutical and Supply Shortages

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Crisis Standards of Care (CSC) originally assumed the conditions causing patients to be placed at risk would be pervasive and due to a catastrophic disaster. During the COVID-19 pandemic, many pharmaceutical products, including vaccines, monoclonal antibodies, and remdesivir, had to be rationed. Even in the absence of a disaster situation, frequent product shortages – such as RhoGAM, blood products, radiologic contrast, chemotherapy agents, blood culture bottles, and intravenous fluids – place patients at substantial risk of a poor health outcome.

With shortages of drugs, blood products, and other diagnostics and therapeutics certain to continue, a proactive approach similar to other CSC processes is required when:

- The shortage is likely to last for days to months and cannot be addressed through alternate suppliers.
- The consequences of not receiving the medication or other product places the patient at increased risk of a poor health outcome.
- There are no reasonable equivalents.

When these conditions are met, actions at both the facility and regional levels are necessary to uphold the CSC principles of fairness, transparency, proportionality, and accountability. To meet these principles, it is essential that healthcare providers are given clear guidelines. These guidelines should provide a tiered approach emphasizing lower risk substitution of alternatives and conservation of the product with higher risk restrictions placed on use as the shortage worsens. Such guidelines promote consistent actions to maintain fairness and access for all patients.

## Regional/State Actions

National medical specialty societies often issue guidelines for restrictions on use of products in shortage that providers can adopt. However, in some cases, these recommendations will be delayed or absent, requiring adoption of guidelines developed at a state or regional level. Many states have a process in which subject matter experts convene to develop recommendations that can be circulated to healthcare facilities and providers (e.g., a State Disaster Medical Advisory Team). If such a process does not exist, a healthcare coalition, hospital association, or other coordination body may also convene a group of experts (e.g., hematology/oncology experts in the case of a chemotherapy shortage) to develop recommendations. Once recommendations are developed, state or regional experts should continue to monitor and discuss the degree of shortage being experienced by the hospitals. In some cases, sharing of products may be necessary (e.g., to ensure trauma and cardiac centers have adequate intravenous contrast for emergency imaging). Continued communication to healthcare providers about the degree of shortage encourages use of best practices across the region or state that are appropriate to the current situation.

## Facility/Health System Actions

At the hospital level, modified incident command should be activated with a director of the affected area (e.g., pharmacy), chief medical officer, chair of the pharmacy and therapeutics committee, or similarly qualified individuals in the incident commander role. Managing critical supply shortages through a structured process to develop and implement triage criteria helps set the expectations and context for disaster situations when other resources may be in shortage and ensures there is leadership support for following the guidelines.

If allocation (triage) criteria are not defined by a regional or state process, the facility or healthcare system may need to determine best practices. In most cases, external guidance will require adaptation to the specific facility services and role in the community. An internal committee with relevant subject matter experts should be responsible for guideline content and/or formatting.[1] Hospital orders and order sets should be configured to adapt to the guidelines and standardized communications provided to staff, patients, and families about the current situation and mitigation strategies. Changes to product availability will be dynamic and require multiple updates to adjust practices and communications to the current situation. Facilities should track and report inventory internally and externally to the coordinating entity for visibility on the degree of shortage, along with information on usual consumption rate and any anticipated delivery dates for additional context.

When possible, restrictions should be integrated into electronic ordering processes; prompts for providers ordering medications/diagnostics in shortage should suggest viable alternatives and reinforce appropriate conditions of use. Opportunities to conserve use should be identified. Alerts should also be placed in the ordering system and special labeling considered when drug concentrations or supplied materials change, which is a frequent issue when usual products are not available. If conservation of dosing is possible, the pharmacy may be able to prepare multiple unit doses from a single vial or doses may be able to be reduced with similar effect (for example, adjusting CT protocols to accommodate lower doses of contrast).

Providers should document when treatments must be restricted due to shortages, and that treatment provided was consistent with recommended guidelines (or why a deviation from guidelines was warranted). A macro/shortcut in the electronic health record can facilitate this documentation. Ideally, if the provider feels that treatment was significantly compromised by the restrictions, the hospital should track these cases and determine if trends require any modification to the guidelines or are a necessary compromise given the resource availability.

State legal protections for crisis situations are rarely invoked and usually do not address the consequences of "routine" supply shortages. This makes it even more important that providers and hospitals coordinate on regional and state strategies, as liability is difficult to prove when a reasonable provider follows recommended strategies that have been implemented in the area.

## Conclusion

Shortages of drugs, blood products, therapeutics, and similar products compromise clinical practice on a daily basis. Most shortages are mitigated by the availability of alternative products and do not threaten patient outcomes. Increasingly, however, a coordinated and proactive approach is necessary to steward resources and

[1] ASHP Guidelines on Managing Drug Product Shortages.

ensure patients whose care is most jeopardized by the shortage receive the necessary resources. Leveraging these opportunities to develop and implement triage strategies at the hospital, healthcare system, regional, and state level greatly facilitates using these constructs and strategies during a disaster. For additional information, review the ASPR TRACIE Pharmacy Topic Collection and Medical Product Shortages and Scarce Resources Page.

***Access the other documents in this collection:***

- CSC Considerations: De-Escalation of Care
- CSC Considerations: Legal/Regulatory
- CSC Considerations: Non-Beneficial Care
- CSC Considerations: Anticipating and Mitigating Crisis Care
- CSC Considerations: Reducing Provider Distress