Medical Product Shortage Framework

July 8, 2026 – DRAFT – VERSION 2

Purpose

In the event of a shortage of medical products, this framework is designed to support healthcare institutions and providers to make fair and consistent decisions about the allocation of scarce medical resources, ensure that critical resources are conserved and distributed efficiently and ethically, and promote transparent decision-making and trust. The Medical Product Shortage Framework may be used by ASPR TRACIE's Clinical Resources for Emergency Shortages of Treatments and Supplies (CRESTS) initiative to guide development of national-level considerations when planning for and responding to medical product shortages. It can also be used at the facility, health system, or regional levels to address their specific needs in alignment with a standardized approach.

Section 1 outlines the framework for ***planning***. It overviews key considerations to inform the allocation of scarce resources, such as the products in shortage, the severity of the shortage, the clinical guidelines for appropriate use, and core ethical principles for consideration. In the event of a shortage, these considerations should be used to guide development of the Medical Product Shortage Template in Section 2.

Section 2 provides the Medical Product Shortage Template for ***response***, which can be adapted to ensure that critical resources are conserved and distributed efficiently and ethically and decisions applied consistently and transparently across healthcare settings.

Ideally, this framework is applied to a shortage at the national (or even international) level for consistency. However, the framework may need to be used or adapted to meet regional, state, and even local conditions.

Section 1: Planning

Assumptions

The general approach[1] should begin with maintaining preparedness for supply shortages and involve a progression (i.e., stepwise approach from least to most risk of harm) of implementing restrictions and strategies including:

[1] Minnesota Department of Health. (2024). Patient Care Strategies for Scarce Resource Situations.

- Conservation – conservation strategies may be more restrictive in relation to degree of shortage (e.g., restricting the use of certain drugs in shortage)
- Substitution – substitution of an equivalent or less effective resource depending on availability (e.g., substituting one antibiotic for another that is in shortage)
- Adaptation – changes in the use of resources to adapt to the situation (e.g., placing two patients on one ventilator)
- Reuse – reusing single use supplies after appropriate cleaning/disinfection/ sterilization
- Prioritization – assigning (or in some cases reassigning) resources to patients with good prognoses

These strategies are generally in order of preference though some aggressive conservation strategies (e.g., withholding specific therapeutics in shortage from some patients) can have major impacts on patient outcomes.

Ethical Obligations

This framework is grounded in two core public health ethical obligations: the duty to steward scarce medical resources to protect population health and the duty to ensure everyone has the opportunity to receive scarce medical resources. The framework attends to the following ethical principles:

- Maximizing benefit: Maximize use of available resources, including prioritizing those most likely to benefit from treatment.
- Fairness: Ensure fair processes for decision-making and that allocation does not exacerbate disparities.
- Transparency and accountability: Communicate scarcity, impact, and strategies employed. Apply consistent criteria for decisions.
- Proportionality: Restrict patient treatments only to the degree necessary, and revise restrictions as availability changes.

The goals of this framework are to support consistent allocation decisions using risk-stratified restrictions, while attending to fair allocation of medical products. Note that this document does not capture the full range of ethical issues for resource allocation. Involvement of ethicists at the local/regional level is an important component of operationalizing restrictions. CRESTS recommendations focus on clinical adaptations rather than the processes of implementation.

Step 1: Activation of Response to Support the Shortage

Initial criteria for developing allocation considerations should be determined by:

1. The absence of the product poses a clear threat of adverse outcomes
2. No acceptable substitute is readily available in sufficient quantities

3. The duration and national significance of the shortage require clinical recommendations for allocation

In the event of a shortage, the template should be updated with the following with input from subject matter experts and using the best evidence available: the product and all forms in shortage, a brief situation overview, and any information provided by the Food and Drug Administration (FDA), the Administration for Strategic Preparedness and Response (ASPR), and other relevant entities to support appropriate adaptations.

Use of the templated strategies in Section 2 should be implemented only if:

1) The supply of the product is, or will soon be, insufficient to treat all patients.

AND

2) The region (e.g., healthcare coalition, Regional Disaster Health Response System) has activated for coordination. This may be limited to information sharing or may involve regional processes for triage and transfer of resources.

Step 2: Identify Strategies to Maximize Product Benefit and Minimize Risk

Responding to a shortage should include strategies to conserve product and mitigate risks. Examples of questions to consider when determining which strategies to implement include:

Supply Strategies

- What are the current vendor allocation strategies?
- Is international product available? If so, what is the timeline for approvals/ importation?
- Are bulk or other forms available that could be aliquoted at the pharmacy level?
- Is compounding an option?
- Can shelf life be extended to allow use of expired products?
- Can beyond use dating (BUD) be extended beyond the USP 795/797/800 requirements?
- Can production and other regulatory restrictions be lifted (e.g., restrictions on 503b companies)?

Restriction Strategies

- Can reduced doses be used effectively to conserve supply in certain situations?
- Can treatment potentially be deferred or intervals prolonged to increase the chance that additional supply will become available?
- Can modifications or restrictions to the patient care setting reduce the quantity of supply needed?

- Are substitutes for some categories of use possible with no or low risk of poor outcomes?
- Are oral or other forms of medication available for at least some conditions?
- Can a reusable product be used as an alternative to a single use product (e.g., powered air purifying instead of N95 respirators, washable instead of disposable gowns)?
- Can another product be safely adapted for use in place of the product in shortage (e.g., modifying a product intended for adults for use in pediatric patients)?
- Can a single unit of use (e.g., vial, tablet, patch) be split, remainder of medication conserved for additional dosing, or doses rounded down safely to prevent use of an additional unit (including following USP 797/800 requirements for sterile dosing)?
- Are there indications that consume a much higher quantity of product? What is the relative risk of restricting use for these conditions versus other conditions that use lower doses?
- What are the indications for the product that are most (and least) beneficial?
- Is the medication used for prophylaxis or palliation and could/should those uses be restricted in favor of active treatment use?
- How many times can a product designed for single use be reused safely?
- Can the product be used for a longer time than its optimal use per the Package Insert (PI) or Instructions for Use (IFU)
- Should use of the product be restricted to patients likely to respond to treatment (i.e., withholding for poor prognosis)?

Information provided by FDA, ASPR, and other relevant entities such as specialty societies can guide the identification or development of a range of strategies and clinical guidance on allocation.

Step 3: Organize Restrictions According to Risk

Once strategies are identified, the tiered system in Table 1 helps categorize the risk posed by restrictions, helps ensure common terminology during coordination activities, and supports proportional restrictions on the product in shortage. According to the indication, develop tiers ranging from:

Table 1 - Definition of Tiers for Risk-Based Restrictions

Tier 1 – Moderate Shortage	**Tier 2 – Severe Shortage**	**Tier 3- Critical Shortage**
Restrictions should pose low risk for adverse patient outcome.	Restrictions pose moderate risk of complication/adverse outcomes for some patient groups, but the overall risk is low.	Restrictions pose significant risk of severe complications/ adverse outcomes and must prioritize those patients who can most benefit.

Tiers are designed to be implemented sequentially in proportion to the local shortage impact. Using colored tiers that correspond to the conventional, contingency, and crisis framework of care supports consistent strategy application as well as providing consistent terminology and ability to compare shortage consequences across multiple facilities or regions. Understanding the degree of shortage and risk in a given area supports providing a consistent standard of care to the population and can help inform supply and allocation decisions. Consultation with subject matter experts and a process at the facility (and potentially regional) level for ethical decision-making is required for prioritization decisions in Tier 3 (e.g., the ASPR TRACIE Hospital Crisis Standards of Care Resource Allocation Annex[2]).

Facility and regional coordination and conservation should begin as soon as the shortage is recognized. A Tier 3 shortage may require additional planning to provide structure and oversight to ensure decisions about care remain fair, transparent, and inclusive—even under constraint. This planning should occur in anticipation of, rather than during Tier 3 conditions. Note that if there are steps within a tier that should be implemented sequentially rather than concurrently (e.g., in Tier 3 some strategies carry higher risk than others), these should be denoted as 3A, 3B, etc.

The process should include review, re-evaluation, and documentation to ensure allocation decisions are made in a manner that is fair, consistent, and transparent. The recommendations should be updated as new information becomes available. As additional products become available, the goal should be to relax restrictions (proportionality) as soon as practical with an end goal to return to normal use.

For facilities and regions to apply restrictions, processes are needed that may include restricted ability for providers to order treatments, specialty consultation required to order treatment, and – potentially – facility, system, or regional review of cases to allocate treatment. However, in most cases this will rely on voluntary cooperation to mitigate resource imbalances – in some cases transferring product or directing patients to facilities with product, among other strategies.

If the described Tier 3 strategies are insufficient, *including* prioritization, the facility and region should have an ethical process for determining access (e.g., lottery).

[2] https://files.asprtracie.hhs.gov/documents/template-hospital-csc-resource-allocation-annex.pdf

Example: Shortage of Radiocontrast Media Strategies
Note: simplified to illustrate tiers

Indication	Tier 1 – Low Risk	Tier 2 – Limited Potential Adverse Outcomes	Tier 3 – Assumed Adverse Outcomes
All imaging	• Consider delaying study if safe • Consider alternative *equivalent* imaging modality (MR, PET, US) • Reduce dosing to minimum acceptable • Adjust scan parameters to accommodate lower volumes of contrast • Split/conserve dosing from sterile vials (if can be performed safely)	• Consider alternative *acceptable* imaging modality • Conduct non-contrasted scan when acceptable • Prioritize acute imaging unless risk of delay is substantial	• Reserve contrast for emergency interventions (e.g., cardiac cath) • Conduct non-contrasted scans that pose a substantial risk of missed pathology (e.g., trauma) • Defer most contrasted imaging to preserve contrast for emergency angio • Prioritize high-consequence imaging studies across disciplines (e.g., oncology, surgery, vascular, GI)

Section 2: Medical Product Shortage Template

Note: The format will be consolidated in posted considerations to remove the steps and background information.

Step 1: Activation of response to support the shortage

Criteria for activation:

- The absence of the product poses a clear threat of adverse outcomes
- No acceptable substitute is readily available in sufficient quantities
- The duration and national significance of the shortage require clinical recommendations for allocation (note: regional coordination is required to ensure consistency of application of strategies)

Product (generic name):

Product forms affected:

Brief situation overview:

Step 2: Identify strategies to maximize benefit and minimize risk

Refer to information provided by FDA, ASPR, and other relevant entities including current and prior specialty society guidance to support appropriate adaptations.

Additional explanation and references may be provided in the following corresponding sections.

Supply strategies:

Restriction strategies:

Each of these strategies should be included in the Tiers table in Step 3 according to risk.

Step 3: Organize strategies according to risk

The tiered system helps assign risk posed by the available strategies, helps ensure common terminology during coordination activities, and supports proportional restrictions on the product in shortage. According to the indication for the product, develop tiers that will be sequentially implemented ranging from:

Tier 1 – Moderate Shortage	Tier 2 – Severe Shortage	Tier 3 – Critical Shortage
Restrictions should pose low risk for adverse patient outcome	Restrictions pose moderate risk of complications/ adverse outcomes for some patient groups, but the overall risk is low	Restrictions pose significant risk of severe complications/ adverse outcomes and must prioritize those patients who can most benefit

Tier 2 and 3 shortages should involve regional coordination mechanisms and may involve consultation and/or team-based decisions —at the facility and/or regional levels—to ensure allocation decisions are made in a manner that is fair, consistent, and grounded in public health priorities.

As shortages worsen, restrictions are implemented in proportion. Use of the tiers promotes consistency of decision-making and ensures common definitions for situational awareness.

Indication	Tier 1 – Low Risk	Tier 2 – Limited Potential Adverse Outcomes	Tier 3 – Assumed Adverse Outcomes
			3A 3B 3C

Additional areas of discussion/operational considerations:

Contributing experts/entities:

Additional considerations:

References: