DEPARTMENT OF HEALTH

# Pharmaceutical Shortages Response Framework

## PLANNING FOR HEALTHCARE FACILITIES AND MDH RESPONSE

## Overview

The intended audience for this document is healthcare facilities who might experience a pharmaceutical shortage. This document describes the framework the Minnesota Department of Health (MDH) uses when shortages of key pharmaceutical products arise, either due to supply chain issues or when demand exceeds available supply, or both. It also describes the actions MDH expects healthcare facilities to take in these situations. *This framework does **not** apply when the pharmaceutical products fall under the permission of an emergency declaration and are being distributed from the Strategic National Stockpile (SNS).*

**This document is not legal advice, it does not carry the force or effect of law, and it should not be construed as a statement of legal or regulatory requirements and protections.** Healthcare facilities or systems implementing strategies to manage critical medication shortages and other crisis situations are strongly encouraged to consult with legal counsel, and coordinate their efforts with health system leadership, Healthcare Coalition (HCC) partners, and MDH.

### Levels of Shortage

The U.S. Food and Drug Administration (FDA) considers a product to be in shortage when, on a nationwide level, supply is not meeting current demand, or if supply is not forecasted to meet current demand. Shortages may be driven by several factors, including low prices, manufacturing complexity, quality concerns, geographic concentration, or manufacturing interruptions due to emergencies. In one example, a shortage of IV solutions occurred when a single facility producing 60% of the U.S. supply was damaged by Hurricane Helene in 2024.

A local product shortage at a single facility or healthcare system may be managed by transferring product from other locations, potentially with assistance from a regional healthcare coalition (HCC) or obtaining alternatives from distributors when available. More details on managing local shortages are available at MDH: FAQ: Pharmaceutical Shortages for Minnesota Hospitals (www.health.state.mn.us/communities/ep/surge/crisis/pharmfaq.pdf). However, more widespread shortages affecting healthcare facilities statewide or nationally may require MDH to convene a crisis standards of care (CSC) response to issue guidance for healthcare systems. For more information on CSC planning for health care facilities, see the MDH: Healthcare Facility Surge Operations and Crisis Care framework (www.health.state.mn.us/communities/ep/surge/crisis/framework_healthcare.pdf).

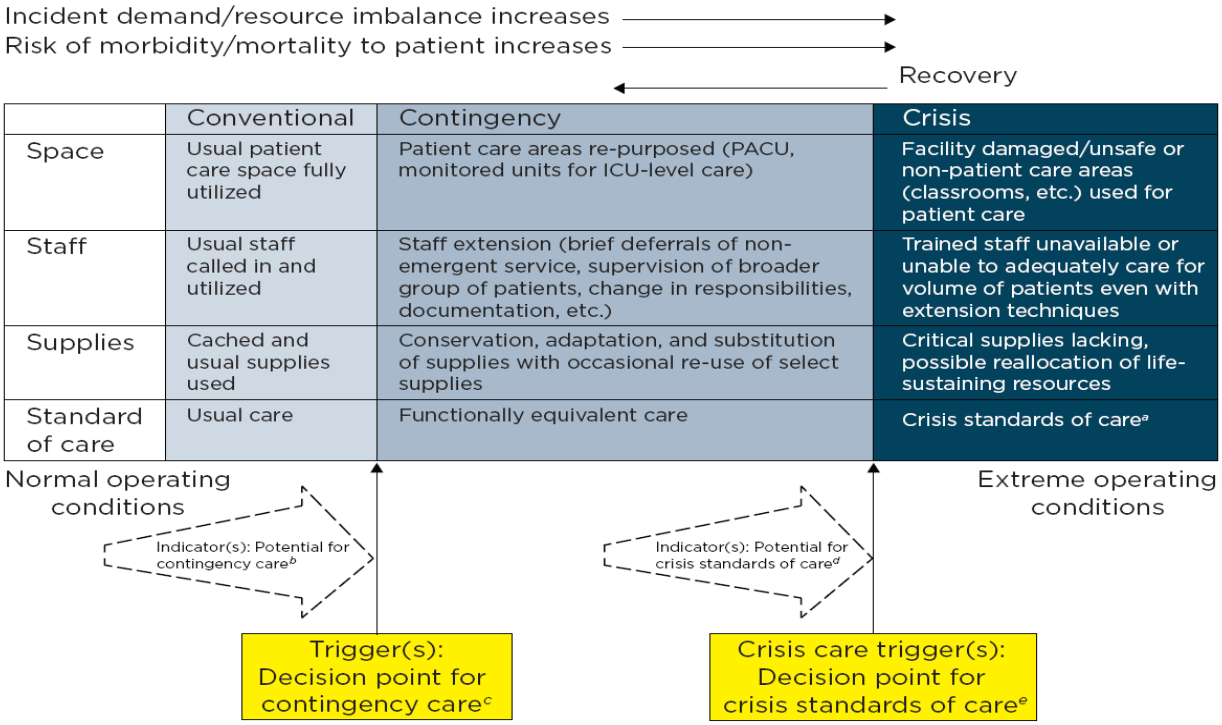
# Management of Scarce Resources

## Continuum of Care

The model of the Continuum of Care is central to understanding responsibilities and strategies for response to changing conditions and evolving levels of resource scarcity during public health events.

Figure 1 (below) illustrates the continuum of care, from conventional care, transitioning to contingency care, and finally crisis care. During conventional care, usual clinical services are maximized (e.g., use of available inpatient beds). During contingency care, care provided is *functionally equivalent* to routine care but equipment, medications, and even staff may be used for a different purpose or in a different manner than typical daily use (e.g., substituting one antibiotic for another with a similar spectrum of activity or safely expanding staff duties beyond their normal scope of practice). The demands of most incidents can be met with conventional and contingency care. Crisis care falls at the far end of the spectrum when resources are scarce and the focus changes from a primary aim on individual patient-focused care to delivering the best care for the patient population. MDH provides ethical guidance for managing the challenges associated with transitions between conventional, contingency, and crisis conditions in a framework available at MDH: Minnesota Crisis Standards of Care (www.health.state.mn.us/communities/ep/surge/crisis/framework_transitions.pdf).

**Figure 1: Allocation of specific resources along the care capacity continuum (Institute of Medicine, 2009)**



In shortage conditions, the following strategies should be used to alter care practices. These strategies should be proportional to the degree of resource shortage. They are:

- **Prepare:** Pre-event actions taken to minimize resource scarcity.
- **Substitute:** Use an essentially equivalent device, medication, or personnel for one that would usually be available.
- **Adapt:** Use a device, medication, or personnel that are not equivalent but that will provide sufficient care.
- **Conserve:** Use less of a resource by lowering dosage or changing utilization practices.
- **Re-use:** Re-use (after appropriate disinfection/sterilization) items that would normally be single-use items.
- **Reallocate:** Restrict or prioritize use of resources to those patients with a better prognosis or greater need.

In general, Substitution strategies can be considered during either conventional or contingency conditions, based on the type and nature of the shortage and substitution. Adapt and Conservation strategies are considered contingency measures, and Re-use and Reallocate strategies are considered crisis measures. ***MDH should be notified if facilities and/or system are moving from conventional to contingency or contingency to crisis standards of care.***

## Healthcare Facility Initial Steps

All facilities should have a structured process in place to address pharmaceutical shortages. This should include working with their HCC to conduct a supply chain integrity assessment to evaluate equipment and supplies that will be in demand during emergencies and develop mitigation strategies to address potential shortfalls. Healthcare systems should reach out to their HCC for more information on conducting this assessment (Regional Health Care Preparedness Coordinators (RHPCs) - MN Dept. of Health (www.health.state.mn.us/communities/ep/coalitions/rhpc.html).

MDH has created Patient Care Strategies in Scarce Resource Situations (www.health.state.mn.us/communities/ep/surge/crisis/standards.pdf) for all healthcare facilities to use in these situations. Principles of crisis standards of care/disaster resource allocation can be used to determine the response necessary. No healthcare facility or health system should operate in a silo if they find themselves in contingency or crisis but should reach out to their healthcare coalition and MDH.

**Universal Actions for Healthcare Facilities to Take for Shortages**

1. Designate a lead (incident manager) for shortages.
2. Develop a process for recognizing and categorizing shortages based on usual use, product on hand, likely delivery, and clinical indications.
3. Define supply levels using common terminology.

   a. Are you discussing number of doses or number of patient courses? A patient course could be multiple doses of a medication or product.
      i. Example: an Rh-negative woman with an Rh-positive infant needs 2 doses of RhoGAM (or equivalent), so therefore 2 doses are equivalent to 1 patient course.
   b. Green/Yellow/Red terminology to describe Conventional/Contingency/Critical levels of supply.
      i. Example: Red signifies less than 1 to 2 weeks of supply based on utilization and doses on hand.
      ii. These definitions are subjective and created by the individual health system. In a statewide response, these should be aligned throughout the state.
4. Determine/define what triggers would prompt movement along the care continuum in both escalating and deescalating directions.
   a. Escalating strategies: Conventional → Contingency → Crisis.
      i. For example, x% of an IV medication order is not fulfilled by wholesaler/distributor. This might trigger an internal review of prescribing criteria and education to providers. A conservation strategy might result in changing utilization practices to use an oral rather than IV formulation of the medication when clinically appropriate. If conservation is not effective, escalating to substitution of an alternative but functionally equivalent IV or oral medication could be considered.
   b. Deescalating strategies: Crisis → Contingency → Conventional
      i. For example, orders go from being missed or sporadically or partly fulfilled to being routinely fulfilled in whole by the wholesaler/distributor. This should trigger the healthcare facility to expand eligibility to receive the medication.
5. For each shortage, ensure that a lead pharmacist works with clinical staff to determine any restrictions on use and work with vendors to determine available alternative medications.
6. Work with distributors to identify alternatives, including non-contract pharmacies or suppliers.
7. Determine the degree of impact on clinical care.
   a. Notify your healthcare coalition in the event of a shortage with significant impact or potential for significant impact on clinical care for situational awareness.
8. Consider centralizing available products where they are most needed or can be allocated.
9. Determine changes to ordering and administration process for alternative agents to assure safety and conservation (particularly if the dosing is unfamiliar).

   a. For example: reduce waste by rounding doses to nearest vial if appropriate, use patient medications from home, and assess the suitability of other pharmaceutical practices such as vial co-mingling, changing concentrations or dose forms, or altering batch times for IV mixing.

10. Provide clinical education and communication regarding the shortage and mitigation measures to providers and patients.
11. Reference Clinical Resources for Emergency Shortages of Treatments and Supplies | ASPR TRACIE (https://asprtracie.hhs.gov/CRESTS) for up-to-date information regarding a particular shortage and/or best practices.

**Regional Healthcare Coalition**

If resources cannot be sourced, facilities should reach out to their HCC via their Regional Healthcare Preparedness Coordinator (RHPC) (https://www.health.state.mn.us/communities/ep/coalitions/rhpc.html)The RHPC will reach out to HCC members to identify supply for sharing and facilities within the HCC may transfer resources. If a shortage cannot be mitigated by sharing within a HCC, the RHPC will reach out to MDH Emergency Preparedness and Response Division (EPR) to notify them of the shortage. MDH cannot purchase products but will work with federal partners and share information on expected duration or shortage and any federal efforts such as distribution from SNS or importation. If necessary, MDH EPR will initiate a CSC response to address the shortage, involving convening meetings to monitor impact, identify best practices, discuss mitigation measures, standardize re-allocation and create prioritization guidance if needed.

# MDH CSC Response to Shortages

This section documents the key steps taken by MDH when responding to a broader regional, statewide or national pharmaceutical shortage.

## Potential MDH Response Actions

| **Prompt** | **Action** |
|---|---|
| FDA adds a medication to their Drug Shortage Database (https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages), indicating awareness of supply situation and that FDA is working with manufacturers on mitigating supply disruptions. | MDH may lean forward to the healthcare systems for information gathering. |
| MDH learns of significant shortage through federal partners, medical organizations, media, or elected officials. | MDH will lean forward to the healthcare system for information gathering. |

| Prompt | Action |
|---|---|
| Manufacturers and/or wholesalers place healthcare facilities medication orders on historic allocation. | If shortage is affecting patient care (i.e., preparation and substitution measures are no longer sustainable), MDH will convene a work group of appropriate subject matter experts (SMEs) as described below to facilitate communication and resource sharing across health systems and create prioritization recommendations as appropriate. |
| Healthcare facility and/or system is no longer receiving full orders of medication. | |

## Roles and Responsibilities

The role of MDH is to convene stakeholders, communicate with federal partners, distribute supplies from SNS if indicated, provide public and provider education and awareness, and draft statewide practices if needed. MDH cannot directly procure products. The assumption is that facilities have implemented basic conservation measures, such as preparation or substitution. MDH should be notified, if not already involved, if facilities are moving from conventional to contingency care or contingency to crisis standards of care.

## Common Framework Development

MDH may recommend to Minnesota's health systems a common framework for prioritizing a resource in shortage. This decreases the likelihood of "shopping" for a resource by patients and encourages transparency throughout the state.

Indicators that a common framework is needed may include:

1. No recommendations, or significant variability in recommendations, from professional societies.
2. No readily available medication alternatives.
3. Shortage is anticipated to last greater than three months.
4. Shortage is resulting in immediate life-threatening effects (e.g. shortage of chemotherapy used with curative intent).
5. Some healthcare facilities in contingency or crisis when others are not.

MDH will conduct a rapid internal review of the developed framework and a rapid external review by response work group members and the Science Advisory Team (SAT). The goal is to disseminate the framework early in response to increase adherence. MDH posts frameworks to the website as well as distributing through appropriate external partner channels (e.g., healthcare coalitions, MHA, SAT, licensing boards etc.).

# Joint MDH and Healthcare Facilities Response

## Work Group Operations

**Lead MDH Division:** Emergency Preparedness and Response, Healthcare Preparedness Section

- Support: Any other division involved or with subject matter expertise. For example, Health Regulations often provide support regarding insurer transparency. Other responses have included the STI program area for the Bicillin shortage and maternal health for the Rhogam shortage.

**Work Group Participants**

- MDH: EPR, medical epidemiologist(s), relevant division representation
- Healthcare Facilities: subject matter experts in clinical area affected, pharmacists, and purchasers as needed
  - Pharmacy representative that can speak to current shortage situation, inventory, projected need, and their communication with and allocation from distributor
  - Clinical representative that can speak to clinical protocols around shortage – substitutions, alternatives, provider education, any allocation or prioritization protocols, patient impact
  - Examples of previous SMEs involved in shortage response:
    - IV Fluids: emergency medicine, critical care, hospitalist
    - Rhogam: OB/GYNs, birthing center providers, hematology
    - Blood Culture Bottles: ID physicians, microbiologist, phlebotomists
    - Chemotherapy: oncology
    - IV Contrast: radiologists
- Healthcare Coalition(s): The RHPCs can act as neutral facilitators to schedule and host workgroup meetings and guide the workgroup through the response.
- Ethics: The University of Minnesota Center for Bioethics often provides in-kind contributions to the development of any prioritization recommendations required.
- Communications: at times healthcare systems may want to include a communications specialist to help craft messages for patients.

**Work Group Meetings**

- Planning meetings: develop a coordination plan for transparent situational awareness amongst all health systems. One or more planning meetings may be necessary in the early phase of the shortage response.
  - Goals for planning meetings:
    - Determine scope and impact of shortage.

        - Develop a definition for reporting status (using red/yellow/green).
        - Develop mechanisms for sharing resources as necessary.
- Need for common framework:
    - There should be agreement among members of the response team and work group that a common framework is necessary, and a request made for development.
    - If a framework is requested, an additional subgroup is typically formed to create an initial draft and bring back to larger workgroup for discussion and to finalize.
- Regular check in meetings:
    - Based on degree of shortage and timeline for expected recovery.
    - Health systems or facilities provide a status report to group (red/yellow/green), supply situation and updates from distributors, mitigation measures in place.
    - MDH reports any federal updates or news related to the shortage and collates mitigation plans for sharing within the group.
    - Framework discussion if implemented or being considered
        - Issues related to framework or implementation challenges

**Deactivation**

- Deactivation of the response may be considered in the event that certain conditions have been met:
    - Examples: Statewide supply levels or majority of healthcare systems are in the green, regular shipments are being received by healthcare facilities by wholesalers, the FDA has declared the shortage over, or a stable alternative is available.
- Close-out meeting:
    - Determining when the shortage has ended and workgroup meetings are no longer necessary.
    - Decision made jointly by MDH and healthcare systems once shortage situation has resolved and mitigation measures are no longer necessary.

# References

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