

Massachusetts General Hospital's Drug Shortages Policy and Procedure^a

Title: Management of Drug Shortages

Applies To: All patient care areas, main campus and offsite

Purpose: To outline the process for evaluating drug shortages, managing resources, and minimizing impact on patient care

Policy

1. The pharmacy department will identify, investigate, and implement alternate purchasing and dispensing practices for drug shortages.
2. The Medication, Education, Safety, and Approval Committee (MESAC) approves any restriction or allocation tactics.
3. Drug purchases can only be made from approved wholesalers or directly from the pharmaceutical company. Refer to: Medication Management Policy: Procurement Section.
4. Drug shortage is defined as "A supply issue that may affect how the pharmacy department prepares or dispenses a product or influences patient care when prescribers must choose an alternative therapy because of supply problems."

Procedure

1. The Pharmacy Medication Management Committee is responsible for monitoring the weekly shortage report under the direction of the chief pharmacy officer and pharmacy inventory and utilization coordinator.
2. The pharmacy will place a medication on the drug shortage list if/when:
 - a. Two unsuccessful attempts to receive a medication from the wholesaler occur
 - b. Drug withdrawal from the market occurs
 - c. Drug recall occurs and is expected to result in a drug shortage
 - d. Drug shortage notification from the market occurs
3. Shortages will be classified as being of medium or critical impact.
 - a. Medium impact—All shortages not deemed to be critical shortages that affect how the pharmacy department prepares or dispenses a product.
 - b. Critical impact—If the shortage affects a medication/product that is used to treat or prevent a serious disease or medical condition for which there is no other alternative drug, available in adequate supply, that is judged to be an adequate substitute, the shortage is termed critical impact.

Note: A mitigation strategy that includes *substitution, restriction, or practice change* in addition to intervention tactics (link below) will be employed when a shortage is deemed critical.

- c. In consultation with pharmacy leadership, the following information may be used to assess the impact of a shortage:
 - Average monthly usage or treatment amount of the affected product
 - Amount on hand/current stock levels of the affected product
 - Availability of other sizes/strengths, etc, of the affected product
 - Ability to get the affected product from other sources
 - Potential for and the availability of a therapeutic substitution
 - Expected duration of shortage
 - Anticipated timeline for supplies to return
4. If a shortage is termed critical, a management strategy will be developed with the assistance of the pharmacy inventory/utilization coordinator, chief pharmacy officer, associate chief of pharmacy for operations, associate chief of pharmacy for clinical services, MESAC Executive Committee, director of systems integration, and the director of pharmacy finance, as well as the clinicians most affected by the shortage.
5. If the drug shortage no longer exists the shortage is termed resolved. A 30-day assessment is required to confirm supply before status change is made.
6. The following intervention tactics may be considered and a decision may be made to:
 - a. Destock automated dispensing machines (ADMs) and centralize distribution from the central pharmacy
 - b. Substitute or utilize therapeutic interchange
 - c. Allocate or restrict
 - d. Create a new/updated medication-specific policy including acceptable alternatives with equivalent dosing information and additional patient monitoring and safety steps requiring MESAC or medical director(s)/chief of service or appropriate designee approval
 - e. Supply alternative in most ready-to use form
 - f. Incorporate software changes (physician order entry, Sunquest, etc)
7. A drug shortage list will be updated and made available to hospital staff throughout the duration of the shortage, and will be located on the MESAC Web site under the drug shortage list.
8. The following communication and education tactics (weekly or as needed) will be considered and employed as needed:
 - a. Notification of MESAC Executive Committee
 - b. Updates to the MESAC Web site

- c. Intervention tactics will be emailed, and/or directly discussed with clinicians (ie, CNS, RPh, RN, medical director(s)/chief of service or appropriate designee)
- d. Medication-specific guideline dissemination
- e. Physician order entry pharmacy-suggested dosing instruction alert(s)

^aNote: This policy and procedure is currently in the review process at Mass General and should not be considered the final, approved policy and procedure at this time.