



Health Services
LOS ANGELES COUNTY

POLICIES AND PROCEDURES

SUBJECT: DHS DRUG SHORTAGE POLICY

POLICY NO: 329.013

PURPOSE:

To provide standardized system drug shortage guidelines to be followed by all DHS institutions focused on maximizing pharmaceutical availability.

BACKGROUND:

Depending on the severity and availability of comparable products, drug shortages may impact patient safety. The American Society of Health-System Pharmacists (ASHP) defines a drug shortage as “a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent.”

Drug shortages are identified via different sources, specifically, the Federal Food and Drug Administration (FDA), ASHP, pharmaceutical distributors, and manufacturers. This policy will delineate the appropriate procedures to be taken at all DHS facilities, as well as centrally through DHS Pharmacy Affairs.

POLICY:

When a drug shortage is identified, an assessment of usage, supply, alternatives and prioritization is performed and a mitigation plan is prepared. During critical drug shortages, the DHS Core Pharmacy and Therapeutics (P&T) Committee may approve plans for restricting use or rationing limited supplies via a supply prioritization plan. This policy serves to augment current DHS facility procedures on managing drugs in short supply.

PROCEDURE:

Upon notification of a formulary drug shortage, DHS Pharmacy Procurement will investigate the drug shortage by contacting the distributor and available manufacturers to determine current availability. DHS Pharmacy Procurement will evaluate formulary drug shortages based on three individual elements. Each element will be evaluated and assigned a severity index rating. The sum of the three elements will determine the manner in which an individual drug

APPROVED BY:
REVIEW

DATES: October 8, 2013

EFFECTIVE DATE: September 1, 2013

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shortage is handled. Drug shortages and severity index ratings will be disseminated to all DHS sites via the "DHS Drug Shortage Bulletin."

The three elements to be evaluated are listed below:

- **Estimated Time to Resolution:** Severity index rating is based on information provided from drug manufacturers, distributors, ASHP and/or FDA websites. Each drug shortage will be assigned a severity index rating corresponding to its estimated time to resolution.

Severity Index Rating	Estimated Time to Resolution
1	Less than 30 days
3	Between 30 to 90 days
5	Greater than 90 days

- **Formulary Utilization:** Severity index rating is assigned based on frequency of utilization within the appropriate therapeutic class.

Severity Index Rating	Formulary Utilization
1	Low frequency
3	Moderate frequency
5	High frequency

- **Potential Patient Safety Impact:** Severity index rating is categorized and assigned based on actions necessary to mitigate potential patient impact.

Severity Index Rating	Potential Patient Safety Impact
1	Drug alternative strengths or concentrations are readily available
5	Formulary therapeutic alternatives are available
10	No therapeutic alternative is available

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1. **Combined Severity Index Rating:** DHS Pharmacy Affairs will notify all DHS pharmacies of drug shortages via the “DHS Drug Shortage Bulletin” and assign severity index ratings for each medication. Combined severity index ratings will be color coded based on Estimated Time to Resolution, Potential Patient Safety Impact and Formulary Utilization. Assigned color codes will initiate its corresponding action plan.

Combined Severity Index Rating	Color Code	Level of Action
3-6	White	Mild
7-11	Gray	Moderate
≥ 12	Black	Severe

2. **Color Coded Action Plan:**

Mild Level: White

- DHS Facilities will maintain focused inventory levels and develop a minimum PAR level based on weekly utilization. Upon reaching minimum Periodic Automatic Replenishment (PAR) levels, DHS Facilities will place order with DHS Pharmacy Procurement for additional supply.
- If medication is available, DHS Pharmacy Procurement will purchase sufficient quantities for each facility orders to maintain continuous supply.
- DHS Pharmacy Procurement will work with the distributor to identify availability based on inventory level and utilization.
- If medication is unavailable, DHS Pharmacy Procurement will investigate potential alternative strengths and concentrations. Each DHS site is responsible for facility communication, training, and education of drug shortage status

Moderate Level: Gray (In addition to Mild Level: White responsibilities)

- DHS Pharmacy Procurement will contact other DHS facilities for surplus stock in an effort to identify potential availability.
- DHS Pharmacy Procurement will be responsible for contacting reliable alternative vendor sources, not previously considered for additional drug availability.

Severe Level: Black (In addition to Moderate Level: Gray responsibilities)

- DHS Pharmacy Affairs in collaboration with the DHS Core P&T Committee, and/or corresponding DHS Expert Panel stakeholders will review system need

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and make appropriate decisions regarding prioritization of use of existing system stock.

- Based on available information, this level represents that supply will be insufficient to meet all system patient care needs. Prioritization of use will be based on restrictions/guidelines dependent on patient diagnosis, care area or by prescriber specialty.
- In the event there is no therapeutic alternative, rationing will be prioritized based on Class A evidence (generally randomized, controlled, published clinical trials and/or FDA approval). DHS Pharmacy Affairs will be responsible for implementing DHS Core P&T decisions of supply allocation.

3. **Transfer of Products between Unlike Accounts (Group Purchasing Organization and 340B)**

During critical drug shortages, when medications are unavailable and unevenly stocked in unlike accounts, facilities may redistribute inventory as needed to meet critical patient need in coordination with wholesaler. Procedures are as follows:

- When medications are available from Group Purchasing Organization (GPO) account and needed for 340B accounts:
 - Step 1: Medications will be returned in the designated wholesaler GPO account. Obtain Medication Return Authorization (MRA).
 - Step 2: Medication will be re-purchased, with the identical National Drug Code (NDC), under the designated 340B account.
 - Step 3: Scan and send all documents to DHS Pharmacy Procurement
 - Step 4: Physically transfer medication to the 340B inventory area for use.
- When medications are available from 340B account and needed in GPO accounts:
 - Step 1: In areas with outpatient services, replenish supply of critical drug shortages with 340B inventory.
 - Step 2: In areas with exclusive inpatient services, medications will be returned to the designated wholesaler 340B account. Obtain Medication Return Authorization (MRA).
 - Step 3: Medication will be re-purchased, with the identical NDC, under the designated GPO account.
 - Step 4: Scan and send all documents to DHS Procurement
 - Step 5: Physically transfer medication to the GPO inventory area for use.

In all cases, maintain copies and documentation of all paperwork and do not return medication to Cardinal.

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4. Inpatient Emergent Therapeutic Substitution Policy

In the event of a critical drug shortage within the inpatient setting where supply is completely unavailable, DHS Pharmacy Affairs in collaboration with DHS Facilities, the DHS Core P&T Committee and/or corresponding DHS Expert Panel stakeholders will determine and approve an alternative medication available for automatic substitution. If a suitable alternative medication is identified for an automatic substitution, DHS Facilities will use the approved automatic substitution medication until the drug shortage has been resolved.

- Approval is required from the DHS Core P&T Committee for any critical drug shortages which will be substituted with an alternative medication.
- DHS Inpatient Facilities will indicate the order change “per Emergent Substitution Policy” on each affected patient medical chart.
- The emergent therapeutic substitution will be followed until the original medication is back in supply. Orders are to be indicated that drug shortage is resolved.

5. Resolution

DHS Pharmacy Procurement will monitor status of drug shortages. Upon resolution, DHS Pharmacy Procurement will remove the corresponding medication from the “DHS Drug Shortage Bulletin”. DHS Facilities are responsible for communication of ongoing shortages to clinicians.

References:

ASHP Guidelines on Managing Drug Product Shortages. *Am J Health-Syst Pharm.* 2009;66.1399-1406.

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