DEPARTMENT: Pharmacy **POLICY: PS-320**

SUBJECT: Drug Recalls

PURPOSE: To establish guidelines for the retrieval of medications recalled or discontinued by the Food and Drug Administration (FDA) or the manufacturer. Drugs that have been discontinued by the manufacturer (but not recalled) are not affected by this policy and may be stocked, dispensed, and administered until the supply is exhausted.

RESPONSIBILITY: Pharmacy Department Staff

DEFINITIONS:
Class 1 Recall is defined as a situation where there is a reasonable possibility that use or exposure to a violative product will cause serious adverse effects or even death.
Class II Recall is defined as situations where use or exposure to a violative product may cause temporary or medicinally reversible adverse health consequences.
Class III Recall is defined as situations in which use of the product is not likely to cause adverse health consequences.

POLICY:
1) Pharmacy personnel are responsible for checking all floor stock, patient medication boxes, and MedDispense units, as well as the stock in the pharmacy.
2) Upon notification of a drug recall from the manufacturer or FDA, the pharmacy will identify and isolate any products covered by the recall. Recalled drugs will be returned to the manufacturer or destroyed, depending on instructions from the manufacturer. Recall records shall be kept on file in the pharmacy for two years.

PROCEDURE:
1) Upon written or telephone notification that a drug has been recalled, the Pharmacy Department will initiate a "Drug Recall Checklist" indicating the drug(s) covered by the recall.
2) A member of the pharmacy team will check all areas of the pharmacy, and other hospital areas where the product may be located.
3) Any amount removed will be documented on a checklist; if none is present, a zero will be entered.
4) Any product returned will be documented.
5) Drug recall checklists will be filed in the department files for reference.

NOTIFICATION OF HEALTHCARE PERSONELL:
1) If the recall has an affect on the availability of medications or the safe use of medications, the Director of Pharmacy shall inform Medical Staff, Nursing, and Administration through the Pharmacy and Therapeutics function. When necessary, (as determined by the Director of Pharmacy,) the medical staff, individual practitioners, or other professionals shall be notified immediately.

NOTIFICATION OF PATIENTS:
1) Patients will be notified based on the classification of the recall and recommendations from the Food and Drug Administration.

REVIEW PROCESS:
- The review process is scheduled for every two years, or as needed.

Drug Recall Checklist:

Name of Product:_____ Manufacturer:_____
Date: _____ Lot: _____ NDC #: _____

Recall Action:

Please complete the following actions regarding the recalled medications. Sign and date when actions are completed and retain this copy for our records.

- No purchase history of the recalled item

Areas Searched:

- Pharmacy Department
- Automated Dispensing Cabinets (Specify Units)

  _____
- Nursing Units (Specify)

  _____
- Refrigerator Units
- Outpatient Infusion Center
- ED
- Radiology
- Ancillary Areas (Specify: Crash Carts, Flight Boxes, etc.)

  _____

Action Executed:

- Product has been segregated from inventory
- Product has been returned via manufacturers specifications
- Hospital notifications sent out to medical staff, nursing, and administration (Attach notifications to this document)
- Patients affected by recall have been notified. (Necessity determined by Director of Pharmacy per FDA recommendation) (Attach notifications to this document)
- No product found, no action required

Completed by: _____ Date: _____