

ADMINISTRATIVE POLICY AND PROCEDURE

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Subject: DRUG RECALL PROCEDURES

Policy No.: A427

Supersedes: February 1, 2016

Review Date: May 15, 2023

Origin Date: April 1, 2000

Revision Date:

POLICY:

A medication may be recalled by the manufacturer or Food and Drug Administration (FDA) for various reasons. To facilitate prompt action and compliance, a systematic means for identification, collection, and disposition of affected medications will be employed.

PROCEDURE:

1. All stock items in the pharmacy and in the nursing units will have an identifying lot number. This number can either be the manufacturer's or the pharmacy's (affixed at the time of compounding or repackaging and retained in a record in the pharmacy).
 - a. All drug orders received in the Pharmacy have stored via computer for each specific drug the **lot number** and **expiration date**, which assists in ascertaining whether a recalled product was ever procured by the Pharmacy.
2. The Pharmacy Chief, or a designee, will review all Drug Recall Notices sent from manufacturers or the FDA.
 - a. The Pharmacy will immediately remove all items concerned from the nursing units and the dispensing areas in the pharmacy, referring to the lot numbers if necessary.
 - b. The Pharmacy Chief, or a designee, will call the Nursing Director's office and Nursing will disseminate information to patient units.
3. All recalled items recovered will be quarantined and then disposed of in accordance with the recall notification.
4. The Medical staff may be notified if warranted, (depending on the seriousness of the recall, through the Pharmacy and Therapeutics Committee of the recall and any information that might be relevant. The P&T Committee will decide whether the product should remain on the Rancho Formulary, in conjunction with input from the DHS P&T Chairs Committee.
5. Outpatients can be located by the following means:
 - a. A computerized Audit Trail report which lists:
 - Patient's name
 - Rancho Los Amigos National Rehabilitation Center's Number
 - Date of Prescription
 - Quantity Issued
6. A review of the original prescription, which indicates the respective **lot numbers** and **expiration dates**, specifically targeting affected individuals.

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Approved By:

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7. Out-patients are contacted by telephone by the pharmacist or a physician/nurse in the service who prescribed the drug. If patient is not available by phone, a telegram or letter is to be sent or a personal visit by a pharmacist is made to alert the patient, depending on the urgency.
8. If the recalled drug is not routinely stocked in the Pharmacy, as verified by procurement records and examination of pharmacy shelves, it is to be documented on the appropriate forms. A copy of the DRUG RECALL MASTER LOG is to be forwarded to the Safety Officer quarterly.
9. If the recalled drug has been received, Pharmacy will investigate and as necessary, a Drug Recall Notice (Attachment I) and a Drug Recall Log (Attachment II) will be sent to all areas.

The Clinic Nurse Manager is to check clinic stock, remove recalled drugs, and return the affected items to the Pharmacy.

The Recall Notice is to be filled out, signed, and returned to the Pharmacy for filing, **even if** no recalled drugs are found.

The Pharmacy will ensure that a copy of all Class I recall notices is forwarded to DHS Pharmacy Affairs and the Chief Medical Officer, as part of the critical event notification procedure. (Copies of all Recall Notices are to be retained on file in DHS Pharmacy Procurement for a period of at least three (3) years. Also, the Rancho Safety Officer is to receive a copy.

The Rancho Safety Officer is to receive a quarterly synopsis of all recall notices received by the Pharmacy.

REFERENCES:

Department of Health Services, Policy No. 329.004
The Joint Commission, TX.3.5.6

ATTACHMENTS:

Drug Recall Notice
Drug Recall Master Log

**LOS ANGELES COUNTY - DEPARTMENT OF HEALTH SERVICES
PHARMACY ADMINISTRATION**

FACILITY NAME: _____

DATE ____/____/____

TO: Service Chiefs
Nursing Area Managers
Administration

FROM: DHS Pharmacy Administration

SUBJECT: **URGENT DRUG RECALL**

We have just been notified that the following drug has been ordered recalled by the (FDA, voluntary recall):

Drug Name: _____

Dosage Form/Strength: _____

Manufacturer: _____

Lot number affected: _____

Reason for recall: _____

Recall class: _____

Please inspect your floor stock and return the recalled drug to the Inpatient Pharmacy or designated area immediately. Document your action in the bottom section.

Thank you.

- I have the recalled drug in my stock and I am returning it to the Inpatient Pharmacy or designated area along with this memo.
- I do not have the recalled drug in my floor stock.

Unit: _____

Nurse Manager's signature: _____

Date: ____/____/____

