

POLICY AND PROCEDURE MANUAL PHARMACY SERVICES		CODE: DATE:	7.10.5 1/5/82
SECTION:	PROCUREMENT	REVISED:	4/19/22 Thinh Tran, Pharm.D
SUBJECT:	DRUG RECALL PROCEDURES	PAGES:	1 of 3

## POLICY

A medication may be recalled by the manufacturer or Food and Drug Administration (F.D.A.) 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 procurement area 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 Food and Drug Administration (FDA).
  - a. Respective Pharmacy personnel 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. If the recalled medication was procured by Rancho, the Pharmacy Chief, or a designee will notify 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.

Reviewed: 7/11/2014bdk, 12/27/2018bdk, 4/19/2022 TT Approved By: Ber Chile



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- 5. Out-patients can be located by the following means:
  - a. A computerized Audit Trail report which lists:
    - (1). Patient's name
    - (2). Rancho Los Amigos National Rehabilitation MRUN or FIN
    - (3). Date of Prescription
    - (4). Quantity Issued
  - b. A review of the prescriptions filled during the date range when the affected lot number(s) and expiration date(s) were stocked in the pharmacy. This will identify the affected individuals' prescriptions.
- 6. 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.
- 7. If the recalled drug is not routinely stocked at either Rancho 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 Office and is reported monthly in their Environment of Care (EOC) meeting.
- 8. If the recalled drug has been received, a Drug Recall Notice [Attachment I) and a Drug Recall Log [Attachment II) is to be sent to all areas.
  - a. The Clinic Nurse Manager is to check clinic stock, remove recalled drugs, and return the affected items to Pharmacy procurement.
  - b. The Recall Notice is to be filled out, signed, and returned to Pharmacy procurement for filing, **even if** no recalled drugs are found.



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- 9. Pharmacy procurement will ensure that a copy of all Class I recall notices is forwarded to 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.
- 10. The Pharmacy will send a monthly synopsis of all recall notices to Rancho Safety Officer and will report the notices in the EOC meetings