

MAIMONIDES MEDICAL CENTER

CODE: PHARM 045 (Revised)

DATE: January 26, 2017

ORIGINALLY ISSUED: October 28, 2004

SUBJECT: DRUG RECALL

I. POLICY:

Upon notification that a drug or pharmaceutical product has been recalled or discontinued by the manufacturer, vendor, or the U.S. Food and Drug Administration (FDA) for safety reasons, the Pharmacy will review the severity of recall notice, actions to be taken, coordinate the removal, sequestering and disposal of such items from all Pharmacy dispensing areas, including RobotRx, MedCarousel and Pyxis stations, medication storage sites, kits that contain medications, all hospital off-site and off-campus areas in which drugs are handled or used.

Upon notification of a product recall or discontinuation for safety reasons, Pharmacy will generate an alert to hospital clinicians, such as prescribers and those who administer medication and will present it to the Medication Use and Pharmacy and Therapeutics Committees. The message would clearly state medication name, manufacturer's name, lot number(s) and reason for the recall.

When Pharmacy is informed of a product recall of substantial clinical significance, patients will be identified, informed of the recall and advised of any necessary action as required.

II. RESPONSIBILITY:

- A. It is the responsibility of the Director of Pharmacy or designee to oversee the management of the drug recall procedure.
- B. Pharmacy will coordinate the identification and notification of patients who may have received a recalled or discontinued medication for safety concerns of substantial clinical significance during their admission or during an off-site ambulatory care area visit.
- C. It is the responsibility of the Inventory Control Manager and the Evening Manager to coordinate the removal of recalled items from all areas.
- D. Risk Management will assist with the notification of patients regarding drug recalls for safety concerns of clinical significance.

PROCEDURES:

- E. Various sources of recall notices (FDA alerts, Distributors, Manufacturers, etc.) are received by the Pharmacy Purchasing Manager.
- F. The Pharmacy Purchasing Manager will review the severity of the recall notice and action(s) to be taken and will discuss with the Director of Pharmacy and/or Pharmacy Safety Officer as appropriate.
- G. The Pharmacy Purchasing Manager will review all electronic invoices and purchase history to determine if the recalled drug has been purchased by the Pharmacy.
- H. The Pharmacy Purchasing Manager will attempt to find out from vendors, distributors, if affected recalled products were purchased, distributed/sent to the Pharmacy Department.
- I. The Pharmacy Purchasing Manager in conjunction with other team members will coordinate the inspection and removal of recalled items from all Pharmacy medication storage areas (as listed in Drug Recall Report Form), including RobotRx, MedCarousel and Pyxis stations, kits that contain medications, Pharmacy satellite locations, Emergency Department, intensive care areas, Anesthesiology, Nuclear Medicine, Radiology, Blood Bank, off-site ambulatory locations, emergency boxes and all other patient care areas in which drugs are handled and used.
- J. Each affected recalled item will be recorded in the "Product Recall" spreadsheet that will include the following information,
- Date of Notice
 - Material Description
 - Material Strength
 - Dosage form
 - Reason for the recall
 - Manufacture item number
 - Manufacturer
 - Manufacturer NDC
 - Affected LOT#
 - Affected expiration date
 - Manufacturer initial shipped date
 - Action taken (specific hospital locations inspected for removal of the recalled items)
- K. To ensure the timely retrieval of all recalled drugs from unit dose dispensing areas including RobotRx, MedCarousel and Pyxis stations and from patients who may be current recipients of the recalled item, the Pharmacy will generate a computerized Target Drug Report for the drug in question. The Target Drug Report will list the name and location of all patients receiving the recalled drug. In the case of product recalls of substantial clinical significance, Pharmacy, in collaboration with Risk

Management, will inform the attending physician and the patient of the recall.

- L. Pharmacy will notify personnel at off-site ambulatory patient care areas of any recalled or discontinued products dispensed by the Hospital Pharmacy. When necessary, owing to a safety concern of clinical significance, each site will identify and collaborate with Risk Management to notify patients and their physicians of the drug recall.
- M. A record of the Drug Recall Report Form will be maintained electronically in Pharmacy's Drug Recall spreadsheet. A copy of the drug recall notice for affected products will also be maintained in the recall section of the Nursing Station Inspection Electronic notification and postings will be made to alert Pharmacy personnel to look for specific recalled drugs during the monthly Nursing Station Review.
- N. The Pharmacy Purchasing Manager will insure that once confiscated, all recalled items will be sequestered, labeled as "Recalled medications" and properly stored in a secure area until they are picked up by or returned to the manufacturer. Recall products from a 340B site will be segregated and returned separately.
- O. The Pharmacy Purchasing Manager will process recalled drugs as directed by the manufacturer or regulatory agency and complete all necessary documentation to denote full compliance with the details of the recall. The completed "Product Recall" spreadsheet and all other documentations will be maintained.

III. CONTROLS:

- A. The Director of Pharmacy will regularly monitor drug recall notices to insure compliance with this policy.
- B. The Director of Pharmacy or designee will periodically review Pharmacy medication storage sites to insure compliance with recall notices as a part of the monthly Nursing Station Inspections.
- C. The Risk Manager will monitor the proper notification of patients who may have received recalled drugs with safety concerns of substantial clinical significance.

Kenneth Gibbs
President & CEO

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REFERENCES:

:TJC Medication Management; American Society of
Hospital Pharmacists

INDEX

:Recall, Drug

ATTACHMENT

: Drug-Recall Report Form

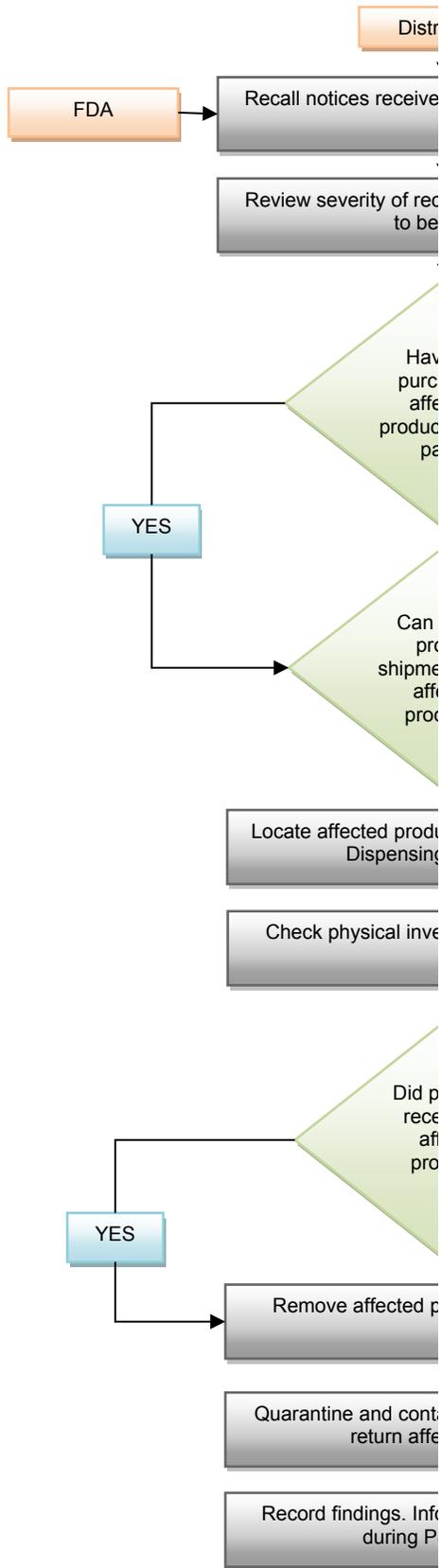


Fig. 1. Drug
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