

MAIMONIDES MEDICAL CENTER

CODE: AD-088 (Revised)

DATE: November 16, 2017

ORIGINALLY ISSUED: October 2, 1990

SUBJECT: Product Safety Recall and Alert

I POLICY

In the event of a product safety recall or alert of a medical device or item, or any equipment, supply or material used by the Medical Center, it is the policy of Maimonides Medical Center to implement prescribed vendor or regulatory agency actions without delay. Product safety recalls and alerts involving pharmaceuticals are addressed in PHARM-045 Safety recalls involving food are addressed in Food & Nutrition policy no. 3.B.13(1) Expired Products and Product Recall (attachment A).

II RESPONSIBILITIES

1. It is the responsibility of any individual who is made aware of a product safety recall or alert of a medical device or item, or any equipment, supply or material to immediately notify their supervisor or department head (or designee) of such notice.
2. It is the responsibility of the supervisor or department head (or designee) to insure timely notification to the Safety Department of the product safety recall or alert notice.
3. It is the responsibility of the Safety Department to forward all safety recall alerts to all departments that may be affected by the notice. If applicable, the department(s) affected will implement the recommended actions on a timely basis and to maintain documentation of the actions related to any product safety recall or alert for biomedical equipment.
4. It is the responsibility of the Senior Vice President for Support Services (or designee) to implement the recommended actions on a timely basis and to maintain documentation related to any product safety recall or alert for equipment or supplies related to the physical plant.
5. It is the responsibility of the Vice President for Professional Affairs to inform the Vice President for Legal Affairs about any product safety alert or recall which may have potential medical-legal implications for the Medical Center.

6. It is the responsibility of the Director of Material Management and Purchasing [or designee] to inform all vendors of their obligation to notify the Purchasing Department in writing by registered letter of any product safety recall or alert, insure timely notification to the user departments, Warehouse and Medical Supply Department, and maintain records related to the notices and documentation of compliance.

III PROCEDURES

1. Any individual becoming aware of a product safety recall or alert must immediately notify their supervisor or department head [or designee] regarding such notice.
2. The supervisor or department head [or designee] should notify the Safety Department of the product safety recall or alert and forward all related documentation.
3. The Safety Department will log all notices and maintain a file of the notices and departmental responses, and follow-up with the departments to assure response is received.

A. Product Safety Recall and Alert – General Products

1. The Safety Department will identify the known and potential user department(s) of the product, and the areas in which stock may be stored and from which distributed, and communicate the recommended actions.
2. The supervisor or department head (or designee) should identify if there are in possession of the identified product, take the actions recommended in the product safety recall or alert, and forward documentation of the actions to the Safety Department.
3. If the product safety recall or alert has potential medical-legal implications, the Sr. Vice President for Professional Affairs will advise the Executive Vice President for Legal Affairs.

B. Product Safety Recall or Alert Involving Bio-Medical Equipment

1. If the product safety recall or alert involves biomedical equipment, the Director of Bio-Medical Engineering is to be immediately notified, concurrent with the notification to the Safety Department.
2. The Director of Bio-Medical Engineering will identify the known and potential user departments of the product, and the areas where the product may be stored or from which distributed.

3. The Director of Bio-Medical Engineering will arrange for compliance with the recommendations of the product safety alert or recall, and coordinate the timely removal, repair or return of the equipment, as appropriate, including coordinating the activities with the product manufacturer.
4. Documentation regarding full compliance with the details of the product safety alert or recall will be maintained by the Director of Bio-Medical Engineering, with copies to the Safety Department.

C. Product Safety Recall and Alert of Equipment, Supplies and Material Related to the Physical Plant

1. If the product safety recall or alert involves equipment, supplies and material related to the physical plant, the Senior Vice President for Support Services (or designee) will be notified by the Safety Department.
2. The Senior Vice President for Support Services (or designee) will identify the known and potential user departments of the product, and the areas where the product may be stored or from which distributed and other areas affected by the product.
3. The Senior Vice President for Support Services (or designee) will arrange for compliance with the recommendations of the product safety recall or alert notices involving equipment, supplies or materials related to the physical plant, and coordinate the removal, repair or return of the equipment, as appropriate, including coordinating the activities with the product manufacturer.
4. Documentation regarding full compliance with the details of the product safety alert or recall will be maintained by the Senior Vice President for Support Services, with copies sent to the Safety Departments.

IV CONTROLS

1. The Director of Materials Management and Purchasing will implement procedures for all vendors from whom products are procured to notify the Medical Center in writing of all product safety recalls and alerts.
2. The Director of Bio-Medical Engineering will include information related to product safety recall and alert in the department's performance improvement reports.

3. The Safety Department will include information related to product safety recall and alert notices in its report to the Environment of Care Committee.



Kenneth D. Gibbs
President & CEO

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REFERENCE: Pharm-045 Drug Recall
INDEX: Alert/Recall of Medical Device(s)/Item(s)
ORIGINATING DEPARTMENT: Safety
LIST OF ATTACHMENTS: Attachment A - Food & Nutrition policy no. 3.B.13 (1)-
Expired Products and Product Recall

ATTACHMENT A

CODE: PHARM 45 (Revised)
DATE: January 26, 2017
ORIGINALLY ISSUED: October 28, 2004

MAIMONIDES MEDICAL CENTER

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.

III. PROCEDURES:

- A. Various sources of recall notices (FDA alerts, Distributors, Manufacturers, etc) are received by the Pharmacy Purchasing Manager.
- B. 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.
- C. The Pharmacy Purchasing Manager will review all electronic invoices and purchase history to determine if the recalled drug has been purchased by the Pharmacy.
- D. The Pharmacy Purchasing Manager will attempt to find out from vendors, distributors if affected recalled products were purchased, distributed/sent to the Pharmacy Department.
- E. 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.
- F. 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)
- G. 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.
- H. 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.

- I. 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.
- J. 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.
- K. 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.

IV. 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
DISTRIBUTION :D (Pharmacy Staff, Selected Administrative Staff)
ORIGINATING DEPARTMENT :Pharmacy

ATTACHMENT : Drug-Recall Report Form

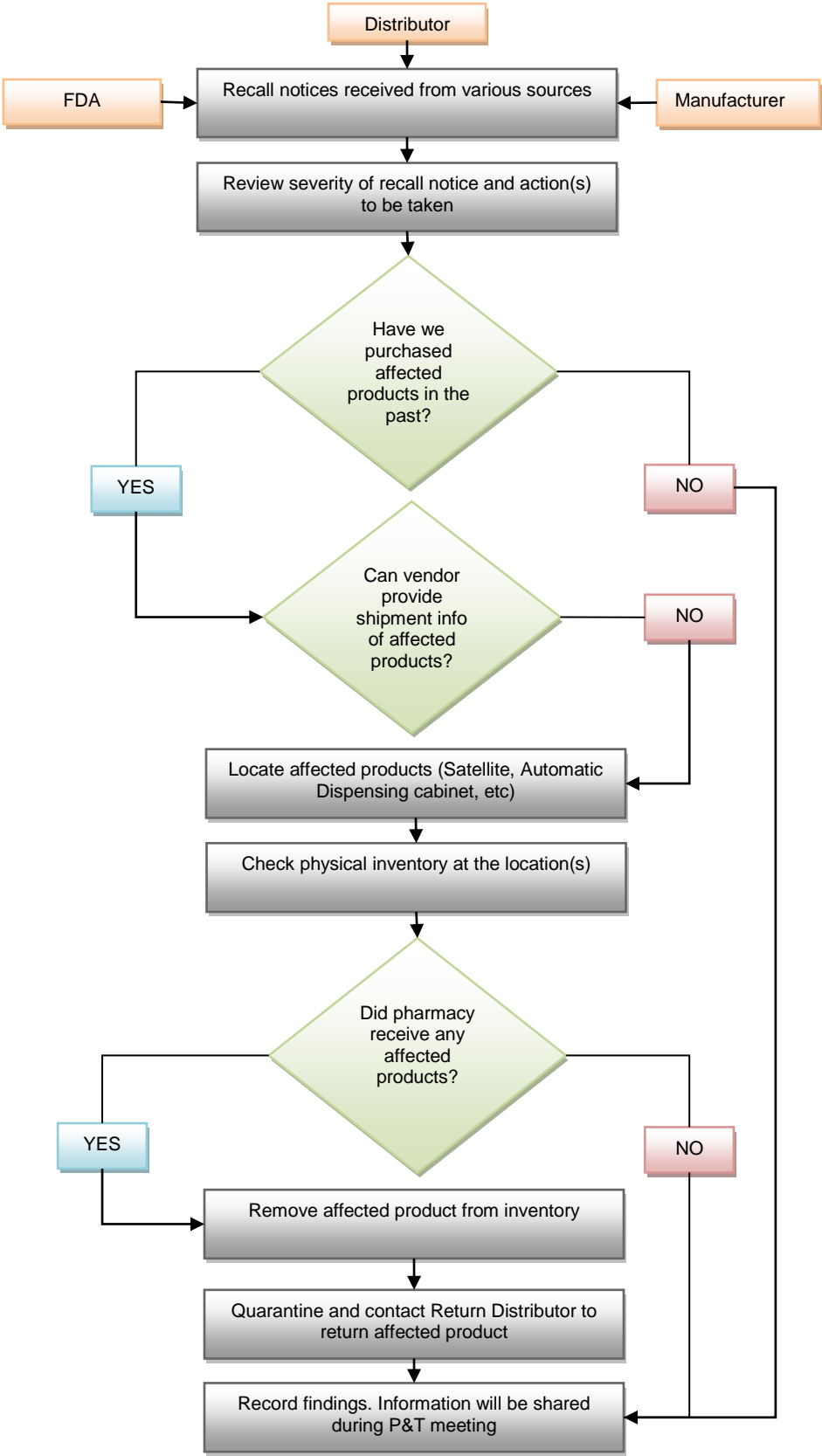


Fig. 1. Drug Recall Flowchart

ATTACHMENT B

MAIMONIDES MEDICAL CENTER

FOOD AND NUTRITION SERVICES POLICIES AND PROCEDURES

Subject: Expired Products and Product Recall	P & P # 3.B.13 (1)	Page 1 of 1
Effective Date: 9/17	Date Reviewed or Revised: Revised 9/17	

Interdepartmental Approval: Marvo Forde

POLICY: Food & Nutrition will discard any outdated food items, and remove food items that are recalled due to manufacturer's defect.

PURPOSE: To establish a policy for handling products identified by the manufacturers for recall and for handling outdated items.

PROCEDURE:

1. All food items that have reached the expiry date will be considered unsafe to use and will be removed from inventory.
2. All items will be checked carefully for the expiry dates to ensure that products are not used after the indicated expiry date.
3. Any unused food items left over after initial use will be discarded.
4. When there is an FDA alert, or a vendor alert, regarding a product being recalled, the lot number, and the manufacturer's name must be provided to the *Department Director* and *Purchasing Manager*.
5. If the alert matches the manufacturer's name and lot number, the products are pulled from the inventory/storage, and isolated in a secured location. The vendor will provide direction of whether the product will be discarded or return them for credit.
6. If the product does not meet the recall lot number, the vendor will send a verification report confirming that the product is not carried nor stocked for the product being recalled.

CONTROL: The Food Service Management Team and Team Leaders are responsible for ensuring compliance to this policy/procedure by all staff members.