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TITLE/DESCRIPTION: **PRODUCT RECALL**			
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APPLIES TO: Pharmacy Division, Logistics Division		**POLICY TYPE:** Multi Disciplinary	

PURPOSE:

1. To provide a written procedure on product recall.
2. To evaluate the effectiveness of the recall procedure and the efficiency, knowledge and responsiveness of staff in conducting the recall procedure.

DEFINITIONS:

Product Recall - a process whereby drugs are pulled out from the market by the drug manufacturers for further studies or for some specific reasons.

Mock Recall - refers to the simulation of recall conducted by the institutions to test the effectiveness of the recall procedure.

RESPONSIBILITY:

Licensed Pharmacists, Pharmacy Technicians, Inventory Staff (Procurement or Logistics) Outpatient Pharmacy Staff, Inpatient Pharmacy Staff, Inventory Supervisor (Outpatient and Inpatient Pharmacy), TQD (QA/ Documentation Section), Procurement/Logistics Supervisor

POLICY:

1. When a recall notice is received, the Pharmacy Inventory Supervisor shall be immediately informed the Inpatient Pharmacy Manager and Outpatient Pharmacy Manager that the drug(s) in question is immediately removed from all storage areas to ensure that the drug(s) is/are not available for use.

2. The Pharmacy Staff shall notify prescribers and individuals involved in prescribing, dispensing and administration of a recalled, damaged, and discontinued medications.

3. Outpatient prescriptions shall be checked by the Pharmacist to determine if any prescription has been dispensed with the lot number in question and patients are informed that their medications have been recalled or discontinued for safety reasons.

4. The drugs shall then be returned, when appropriate, to the recalling government agency or manufacturer. The quantity of the recalled drug shall be indicated on the original notice and kept on file in the Pharmacy Department for future reference.

5. All product recalls shall have a written notice/ request from the pharmaceutical company specifying the particular drug, detailing its dose, dosage form, and lot number, and should be

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addressed to the Logistics Division Officer.

6. A duplicate copy shall be submitted to the Pharmacy Inventory Supervisor for filing.
7. Actual inventory count of pulled-out drugs shall be made upon removal of drugs from the shelves.
8. Internal memo shall be issued by the Inpatient Pharmacy Manager after the removal of the drug from the Drug Formulary.

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PROCEDURE (SOP):

PRODUCT RECALL

- When a recall notice is received, the Pharmacy Manager will be immediately informed and the drug(s) in question is immediately removed from all storage areas to ensure that the drug(s) is not available for use.
- The pharmacy will notify the prescribers and individuals involved in prescribing, dispensing and administration of a recalled, damaged, and discontinued medications.
- The drugs are then returned, when appropriate, to the recalling government agency or manufacturer. The quantity of the recalled drug in indicated on the original notice and kept on file in the Pharmacy Department for future reference.

1. Logistics Division Officer informs the Pharmacy that a written request/notice for recall from the pharmaceutical company specifying the particular drug, detailing its dose, dosage form, and lot number was received.

2. Pharmacists check and retrieve the recalled drug, if available, from all storage and dispensing areas of the hospital (Pharmacist):
   - 2.1 For drugs recalled by a memorandum from FDA, the drug for patient safety is immediately halted from dispensing.
   - 2.2 The areas inspected include mainly the pharmacy store room and all other pharmacy dispensing areas (e.i., Inpatient or satellite pharmacies, outpatient pharmacy, etc.)
   - 2.3 For drugs on a floor stock list, designated pharmacy staff checks and retrieves them from the nurses' stations.
   - 2.4 Designated pharmacy staff determines inpatients who are currently receiving the recalled medication; checks the individual unit dose bin and/or refrigerator at the nurses' station.

3. Judge the severity of the Recall and convene an urgent meeting of the Pharmacy and Therapeutic Committee (Inpatient Pharmacy Manager or Supervisor). All recalled drugs will be classified accordingly:
   - 3.1 Class I: A situation in which the use of, or exposure to a violated health product may cause permanent or irreversible adverse health consequences.
   - 3.2 Class II: A situation in which the use of, or exposure to a violated health product may cause temporary or medically reversible adverse health consequences or where the probability of

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serious adverse consequences is remote.

3.3 Class III: A situation in which the use of, or exposure to a violated product is not likely to cause adverse health consequences.

4. Pharmacist in-charge and Inventory Staff isolates all quantities of the recalled drug in a secured area for processing as per instructions which should be explicitly contained in the department recall notice.
   - 4.1 The pharmacy store room is the designated area for storing all recalled drugs.
   - 4.2 The recall products are quarantined until returned to the manufacturer/destroyed as per manufacturer's instruction.
   - 4.3 All recalled drugs are labeled "RECALLED" to ensure that they will not be inadvertently used.

5. Maintain a file which contains information concerning each drug recalled. The record should contain:
   - 5.1 Generic name
   - 5.2 Trade name
   - 5.3 Company's name
   - 5.4 Lot number
   - 5.5 Manufacturing date
   - 5.6 Expiration date
   - 5.7 Quantity of the drug; if available

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MOCK RECALL

- A mock recall simulates the actual recall procedure of the institution in order to evaluate efficiency and identify gaps in the process.
- A mock recall has to confirm the efficient collation of batch history details and effectiveness of communication channels.
- The mock recall is conducted ideally on an annual basis on years where there are no actual product recalls.
- A product recall team will serve as the point-persons in an event of product recalls. They are the ones tasked to spearhead the mock recall process.
  - The team includes:
    - Inventory Staff (Personnel from Procurement or Logistics), Outpatient Pharmacy Staff, Inpatient Pharmacy Staff
- An audit team will be assigned to document and evaluate the mock recall process.
  - The team includes:
    - Inventory Supervisor (Outpatient and Inpatient Pharmacy), Total Quality Division (QA or Documentation Section), Procurement/Logistics Supervisor
- A corrective and preventive action plan will be reported and documented after conducting the mock recall process.

1. The product recall team sets a random date to conduct the mock recall procedure and records the details in the Mock Recall Form.
2. The product recall team identifies a certain lot and batch of a product that would be used for the recall and indicates in the Mock Recall Form. A scenario is provided as to the class of recall conducted based on the product recall policy.
3. Traceability and recall procedures (DPOTMH-J-P21-S01) are conducted and areas involved are alerted to the mock recall process.
4. The 1 hour time-frame is documented by the mock recall team on the report form.
5. The audit team records any discrepancies observed on the report form after the product recall form endorses to them the report.
6. The audit team provides a CAPA report and to be completed within 7 business days after the mock recall procedure.
7. Inpatient and Outpatient Pharmacy Staff document and file all mock recall reports.

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WORK INSTRUCTION:

PRODUCT RECALL

KEY TASKS	PERSON RESPONSIBLE
1. Checks and retrieves the recalled drug from all storage and dispensing areas of the hospital.	Pharmacist/ Pharmacy Technician/ Inventory and Logistics Division personnel
2. Judges the severity of the recall and if deemed necessary, convenes an urgent meeting of the Pharmacy and Therapeutic Committee.	Pharmacist/ Pharmacy Technician
3. Isolates all quantities of the recalled drug in a secured area for processing within the department.	
4. Maintains a file which contains information concerning each drug recalled.	

MOCK RECALL

KEY TASKS	PERSON RESPONSIBLE
1. Sets a random date to conduct the mock recall procedure and record the details of the mock recall in the Mock Recall Form.	Product Recall Team
2. Identifies a certain lot and batch of a product that would be used for the recall and this will be indicated in the Mock Recall Form and provide a scenario as to the class of recall conducted based on the product recall policy.	
3. Documents the mock recall report form time-frame.	
4. Records any discrepancies observed on the	Audit Team

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report form.	
5. Provides a CAPA report and to be completed within 7 business days after the mock recall procedure.	
6. Documents and files the mock recall reports.	Inpatient and Outpatient Pharmacy Staff

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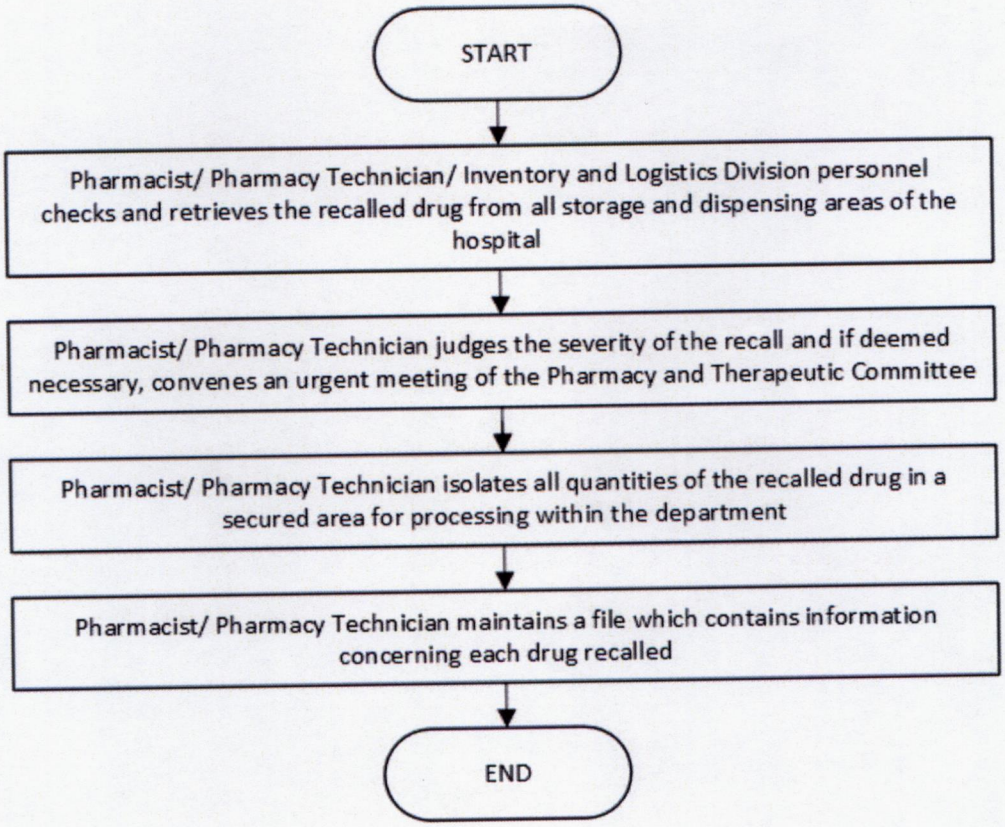
WORK FLOW:

PRODUCT RECALL



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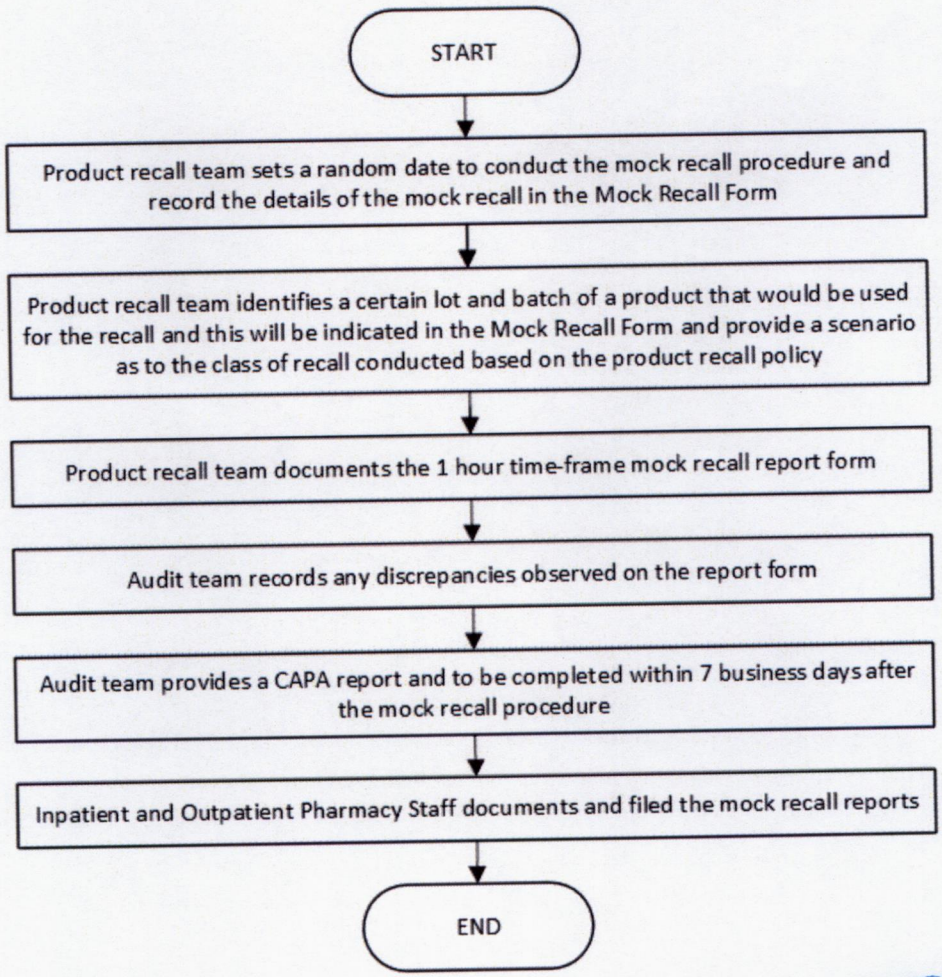
MOCK RECALL



RIVERSIDE MEDICAL CENTER, INC.

DR. PABLO O. TORRE MEMORIAL HOSPITAL

METRO PACIFIC HEALTH
THE HEART OF FILIPINO HEALTHCARE

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FORMS:
PHARM-F002 (01)

EQUIPMENT: N/A

REFERENCES:

1. ASEAN Guidelines on GMP for Traditional Medicines / Health Supplements – 2015 Chapter 9 - Complaints and Product Recall
2. DPOTMH DCN: PHARM- QP-18, Product Recall, 01-01-09
3. DPOTMH-J-P21-S01, Product Recall, 06-30-2022
4. Guidelines on the Recall of Health Products Regulated by the Food and Drug Administration 2023

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