



INODAYA Hospitals - Kakinada

Documentation code:

INH/MOM.Doc.No:17

Policy on Drug Recall

Prepared date: 11/11/2025

Reference: MOM.6.b.c..NABH Standards – 6th Edition

Issue Date: 11/11/2025

Issue no: 02

Review No: 1

Review date: 10/11/2026

1.0 Purpose:

To ensure a prompt, systematic, and safe removal of defective, contaminated, substandard, or potentially harmful medications from all areas of Inodaya Hospital, thereby safeguarding patient safety and complying with statutory regulations.

2.0 Policy:

Inodaya Hospital is committed to acting **immediately and effectively** on any drug recall issued by regulatory authorities, manufacturers, or identified internally. All recalled drugs must be promptly identified, segregated, documented, and removed from patient care areas to prevent accidental use.

3. Scope

This policy applies to:

- Main Pharmacy & Satellite Pharmacies
- All Inpatient Wards
- ICUs, OT, Emergency & Day Care Units
- Store & Central Drug Warehouse
- Nursing Units and Clinical Departments
- Procurement Department

Prepared by: 	Verified by: 	Approved by : 
Mr.Naresh	Dr.Gowtham Krishna	Mrs.Lakshmi Lavanya
Incharge - Pharmacy	Medical Director	Chief Executive Officer



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4. Types of Drug Recalls

A. Class I Recall

- Highest risk; use/exposure can cause serious injury or death.
- Requires **urgent action** within 24 hours.

B. Class II Recall

- May cause temporary or medically reversible harm.
- Action must be completed within 48–72 hours.

C. Class III Recall

- Unlikely to cause adverse health consequences; usually due to labeling, packaging, or quality issues.
- Action within 7 days.

5.0 Procedure:

Sources of Drug Recall Notification

- Central Drugs Standard Control Organization (CDSCO)
- Drug Control Administration
- Manufacturer/Distributor alerts
- Wholesaler notifications

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- Internal quality complaint or adverse event report
- Hospital Pharmacovigilance Committee

5.1 Identify and remove recalled medication from shelves immediately.

- Check batch numbers, stock registers, and dispensing logs.
- Update the **Drug Recall Register**.
- Quarantine recalled drugs in a designated area until disposal/return.
- Inspect all ward stocks for recalled medications.
- Return affected stock to pharmacy immediately.
- Sign off the recall alert acknowledgement form.

5.2. All the expired / damaged / contaminated medications shall be returned to the vendors periodically.

5.3 To record and separate short expiry items from stock before three months of expiry date and will be returned to source of supply.

5.4 In case of banned / discontinued medications, information is received from the concerned manufacturers / stockiest / distributors / medical representatives. With immediate effect the list of banned medications with batch number shall be communicated to all the branches where by the banned medications shall be received and returned to concerned suppliers / manufacturers.

The same shall be communicated to all the concerned departments immediately.

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6.0 Responsibility:

- ✓ Medical Superintendent
- ✓ Nursing Superintendent
- ✓ Procurement Officer
- ✓ All Pharmacy Units
- ✓ Hospital Quality Department

MOM 1C. POLICY ON NEAR EXPIRY MEDICATION

1. Purpose:

To ensure patient safety and prevent the use of medications that are near expiry by establishing a systematic process for identification, segregation, reporting, and appropriate disposal or return of near-expiry medications in Inodaya Hospital.

2. Policy:

Inodaya Hospital ensures that all medications stored or dispensed within the facility are within safe shelf-life limits. Medications identified as near expiry must be removed promptly from patient-care areas, documented, and managed according to hospital procedures to avoid accidental administration.

3. Scope

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This policy applies to:

- Pharmacy (Main and Satellite)
- All inpatient wards
- ICU, OT, Emergency Department
- Outpatient clinics
- Stores and inventory management staff

4. Definition

Near-Expiry Medication: Any medication that is **within 6 months of its expiry date**, unless otherwise specified by hospital management or supplier agreements.

(High-cost or short-shelf-life medications may follow a stricter threshold—e.g., 3 months.)

5. Procedure:

- All near expiry drugs in ICUs and Wards, crash carts, are checked on monthly basis by pharmacist's onsite of area incharge
- All near expiries (**3 months before expiry**) will be removed from the above said areas by pharmacists.
- They are placed in a designated "Near-Expiry Quarantine Shelf" in the pharmacy store.

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- Quarantine area must be locked and labeled.
- Record in the **Near-Expiry Medication Register:**
 - ✓ Name of drug
 - ✓ Batch number
 - ✓ Quantity
 - ✓ Expiry date
 - ✓ Location found
 - ✓ Action taken
 - ✓ Responsible staff signature
- All removed near expiry drugs will be sent to respective dealers before three months and same will be documented.
- Record in the **Near-Expiry Medication Register:**
 - ✓ Name of drug
 - ✓ Batch number
 - ✓ Quantity
 - ✓ Expiry date
 - ✓ Location found
 - ✓ Action taken
 - ✓ Responsible staff signature

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Dispensing Control

- Pharmacy ensures no medication within 3 months of expiry is dispensed, especially:
 - High-value drugs
 - IV fluids
 - Emergency drugs
 - Oncology medications

Monitoring & Audit

- Monthly internal audits by Pharmacy & Quality Department.
- Random checks during ward rounds by Quality Team.
- Non-compliance is reported to the **Medical director** for corrective action.

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