



PHARMACY & MEDICATION MANAGEMENT MANUAL



Annual Documents adequacy & Change Requirements Review

| Sr.No | SOP /Doc No | Documents Name | Issue. No | Rev.No | Review Date | Change | Rev No | Revision Date | Reason for Change | Amendment |
|-------|------------------|--|-----------|--------|-------------|--------------------------------|--------|---------------|--------------------------------|--------------------------|
| 1 | SDH/Pharma/01 | Contents | 1 | 1 | 20-Nov-22 | No Any Change Review Completed | 1 | 20-Nov-23 | No Any Change Review Completed | No Any Amendment History |
| 2 | SDH/Pharma/02 | Organization chart | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 3 | SDH/Pharma/03 | Roles and Responsibilities | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 4 | SDH/Pharma/4.1 | Medication Mgmt Policy-General | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 5 | SDH/Pharma/ 4.2 | Medication storage | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 6 | SDH/Pharma/ 4.3 | Medication - Prescription and Ordering | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 7 | SDH/Pharma/ 4.4 | Medication- Verbal orders | 1 | 1 | 27-Jun-22 | Policy updates | 1 | 20-Nov-23 | As per NABH NC | Policy updates |
| 8 | SDH/Pharma/ 4.5 | High risk Medication Policy | 1 | 1 | 20-Nov-22 | No Any Change Review Completed | 1 | 20-Nov-23 | No Any Change Review Completed | No Any Amendment History |
| 9 | SDH/Pharma/ 4.6 | Medication Dispensing issue | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 10 | SDH/Pharma/ 4.7 | Medication- Patients Own Medicine | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 11 | SDH/Pharma/ 4.8 | Medication Administration | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 12 | SDH/Pharma/ 4.9 | Medication- Adverse drug Reaction | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 13 | SDH/Pharma/ 4.10 | Medication Error | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 14 | SDH/Pharma/ 4.11 | Medication- Narcotics | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 15 | SDH/Pharma/ 4.12 | Medication Chemotherapy | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 16 | SDH/Pharma/ 4.13 | Medication- Implantable Prosthesis | 1 | 1 | | | 1 | 20-Nov-23 | | |
| 17 | SDH/Pharma/ 4.14 | Central Pharmacy | 1 | 2 | 20-Nov-22 | | 1 | 20-Nov-23 | | |

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| 18 | SDH/Pharma/ 4.15 | Retail Pharmacy | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 19 | SDH/Pharma/ 4. 16 | QA for Pharmacy | 1 | 1 | 20-Nov-22 | | 1 | 20-Nov-23 | | |
| 20 | SDH/Pharma/ 4.17 | Medication Recall | 1 | 0 | 27-Jun-22 | Medicine return to the pharmacy | 1 | 20-Nov-23 | As per NABH NC | Medicine return to the pharmacy |
| 21 | SDH/Pharma/ 4.18 | Measure to prevent catheter and tubing misconnection during medication administrations | 1 | 0 | 27-Jun-22 | Catheter & tubing miss connection | 1 | 20-Nov-23 | As per NABH NC | Catheter & tubing miss connection |
| 22 | SDH/Pharma/ 5.2 | Purchase system Policy | 1 | 1 | 27-Jun-22 | Vendor selection vendor evaluation | 1 | 20-Nov-23 | As per NABH NC | Vendor selection vendor evaluation |
| 23 | SDH/Pharma | Pharmacy Department Incharge | 1 | 1 | 27-Jun-22 | No Any Change Review | 1 | 20-Nov-23 | No Any Change Review | No Any Amendmen t History |
| 24 | SDH/Pharma | Pharmacy Department | 1 | 1 | 27-Jun-22 | Completed | 1 | 20-Nov-23 | Completed | |
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| | | 01 November 2021 | 20 November 2023 | | 20 November 2024 | | 1 | | | |
| Reviewed & Prepared By | | | Recommended By | | | | Approved By | | | |
| Mr.Deepak Kale | | Mrs.Shraddha suryavanshi | Dr.H.Kalgaonkar | | | | Dr.S.S.Deepak | | | |
| Pharmacy HOD | | Quality Co-ordinator | Chief Medical Administartor | | | | Chairman & Managing Director | | | |

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Suryavashi

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| 1 | SDH/Pharma/01 | Contents | 1 | 1 | 05-Mar-21 | No Any Change Review Completed | 1 | 20-Nov-22 | No Any Change Review Completed | No Any Amendment History |
| 2 | SDH/Pharma/02 | Organization chart | 1 | 1 | 01-Nov-21 | | 1 | 20-Nov-22 | | |
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| 19 | SDH/Pharma | Pharmacy Department | 1 | 1 | 01-Nov-21 | 1 | 20-Nov-22 |

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| Reviewed & Prepared By | | Recommended By | | Approved By | |
| Mr.Deepak Kale | Mrs.Shraddha Suryavanshi | Dr.H.Kalgaonkar | | Dr.S.S.Deepak | |
| Pharmacy HOD | Quality Co-ordinator | Chief Medical Administartor | | Chairman & Managing Director | |





SAIDEEP HOSPITAL

PHARMACY & MEDICATION MANAGEMENT MANUAL

Amendment Sheet

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| Doc No | SDH/MOM/01 |
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| Sr. No | Page No | Clause No | Date of Amendment | Amendment Made | Reasons | Signature of Approval Authority |
|--------|---------|-----------|-------------------|--|------------------------------------|---------------------------------|
| 01. | 4.4 | MOM 4.E | 27-Jun-22 | Medication- Verbal orders | Policy updates (As per NABH NC) | |
| 02 | 4.17 | MOM 6.B | 27-Jun-22 | Medication Recall | Medicine return to the pharmacy | |
| 03 | 4.18 | MOM 7.H | 27-Jun-22 | Measure to prevent catheter and tubing misconnection during medication administrations | Catheter & tubing miss connection | |
| 04 | 5.2 | MOM | 27-Jun-22 | Purchase system Policy | Vendor selection vendor evaluation | |
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| Dr. Hrishikesh Kalgaonkar | | Dr. S. S. Deepak | |
| Chief Medical Administrator | | Chairman & Managing Director | |



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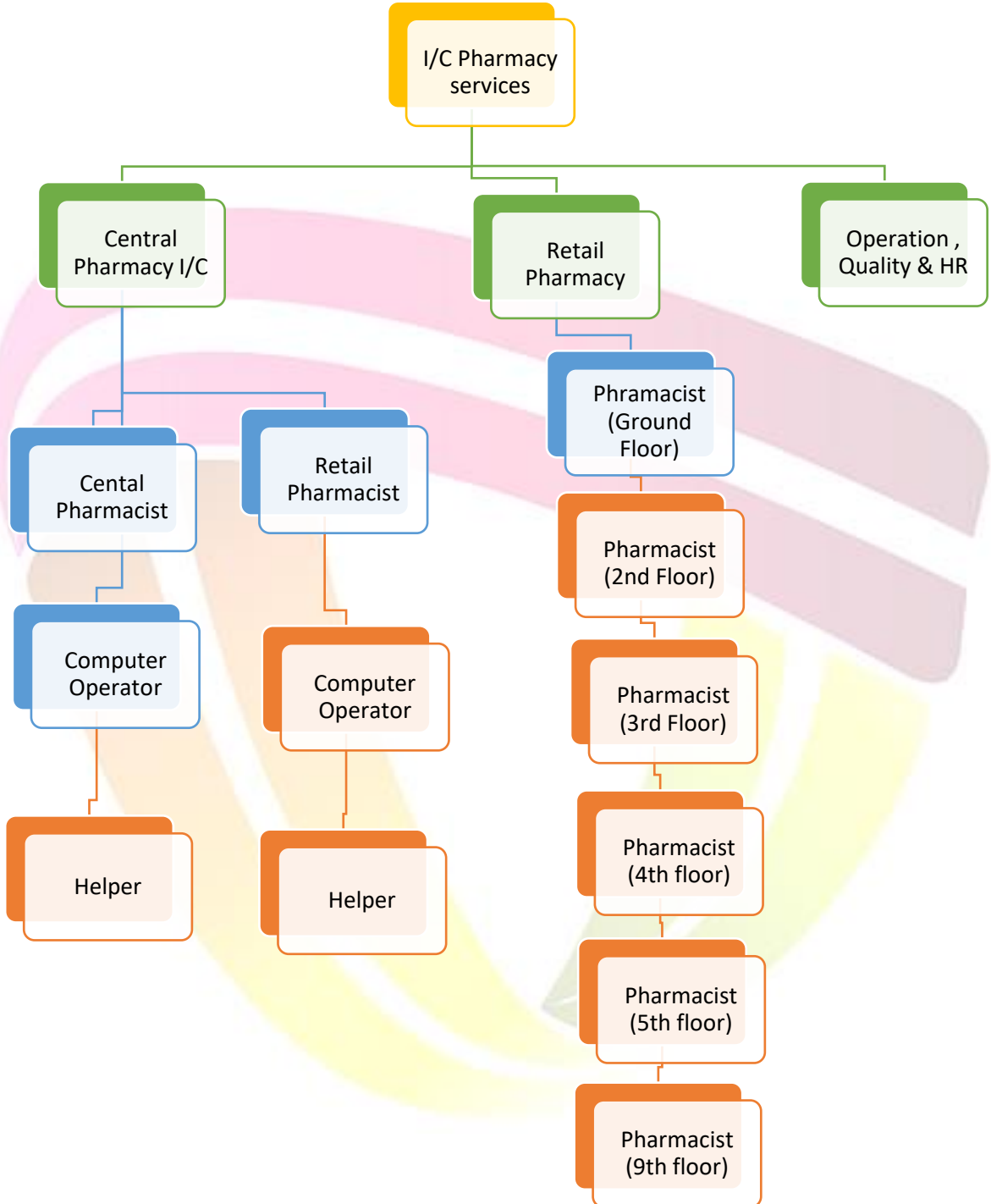
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Organisational Chart – Pharmacy Services



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| Dr. Hrishikesh Kalgaonkar Chief Medical Administrator | | Dr. S.S. Deepak Chairman & Managing Director | |




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Document Title : Roles &Responsibility



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| Document Title : General Policies Pharmacy Services & Medication Management | | | |

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|---------------------|--|
| SUMMARY | <p>This document provides instruction and guidance to hospital staff on various issues related to pharmacy services and management of medication in the hospitals.</p> <p>The policy discusses the overall compliance to various standards pertaining to the Medication Management as per NABH standards; and links to further downstream policies and documentation established for compliance to standards specific to various issues like storage, ordering, administration, adverse reactions etc.</p> |
| DISTRIBUTION | To all departments, units and wards through the Pharmacy and Medication Usage Manual |

INTRODUCTION

This policy has been formulated to ensure as far as possible compliance to various standards pertaining to Management of Medications (MOM) as prescribed by the NABH Accreditation Standards.

PURPOSE AND SCOPE

The purpose of this policy is to guide the hospital staff in managing the process of medication management at various units of the hospital to ensure patient safety and wellbeing.

RESPONSIBILITIES

Chairman & Medical Director:



The overall responsibility of implementing the policy rests with the CMD of the hospital.


HODs / Unit Heads

They are responsible for implementing the various guidance in terms of ordering and administration of medications.

Director In-charge– Pharmacy

Is responsible to ensure that the policies pertaining to pharmacy services are implemented.

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POLICIES

A. Pharmacies

The hospital operates the following pharmacies;

Central Pharmacy: Upper Basement

OPD Pharmacy: Upper Basement & Ground Floor

IPD Pharmacies: On Floors 2,3,4,5,6 and 9th.

The Chief Pharmacist is responsible to ensure that these pharmacies to operate under updated and suitable licenses issued by the state drugs authority.

B. Drugs & Pharmacy Committee

The hospital has a Drugs & Therapeutic Committee which is multi-disciplinary in nature and the committee is empowered to establish and monitor an effective medication management system in the hospital.

The constitution and working system of the committee is described in the relevant section of the hospital manual.

C. Drug Formulary



The hospital formulary shall be made available in all wards and department for easy reference. The same shall be accessible through the Hospital network.


The same is approved and periodically reviewed by the Drugs & Pharmacy Committee. All updating / amendments of the formulary have to be approved by the DPC.

There are certain medications which are prepared in the hospital itself.

At times the hospital allows IP patients to procure medicines from outside, during situations like when the prescribed medicine is either out of stock or not included in the hospital's drug list or the patient wishes to purchase medicines from outside.

D. Purchasing and Procurement

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The method of purchase of a drug in the pharmacy is by inviting tenders from the manufactures/wholesalers.

The Central Pharmacy will be the only purchasing and procurement point for medicines in the Hospital. The detailed procedure governing the purchase of medications is specified in the Pharmacy Services SOP.

The purchasing and procurement of drugs are controlled by the Drugs & Therapeutic Committee established by the hospital.

E. Policy for the Introduction of New Drugs

Introduction of a new drug in the hospital is based on the doctor's indent which, has to be approved by the drugs and therapeutic committee.

The procurement of a new drug is done by issuing purchase orders to the manufacturers/wholesalers.

All patients of Saideep Hospital & Research Pvt Ltd will be prescribed all the medicines they clinically require, based on their diagnosis from the hospital formulary.



To ensure the best use of resources there is a formal procedure for the introduction of new drugs. No new drug will be prescribed without prior authorization from the Drug and Pharmacy Committee.


For inclusion of the new drug in the formulary an application for the same would be sent to the Medical Superintendent. (Refer to the Bylaws of the Drugs & Pharmacy Committee)

F. Obtaining of Drugs not listed in formulary

The method adopted to get an emergency drug that is not there in the formulary is done by:

- Identifying the different brands and manufacturers of the drug.
- Contacting the manufacturers/wholesalers/other hospitals.
- Placing an emergency purchase order.

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On specific request the pharmacy will make arrangements for procurement of the same. This shall be done only in cases where the same is ordered through a prescription by the Head of Departments / Senior Consultants.

All such instances will be reported to the Chief Pharmacist on a weekly basis and subsequently DTC by the him / her on a monthly basis

G. Retail Pharmacy Operations.

The method adopted by the retail pharmacy outlets in dispensing the drugs includes:

- Receiving the prescription on the basis of the queue.
- Billing the prescription.
- Issue of token on cash payment?
- Retrieving the medicine on the basis of the bill.
- Checking the medications retrieved on the basis of the prescription.
- Calling the token and issuing the drugs explaining to the patient regarding the drug intake, dos and don'ts etc.


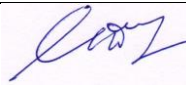
H. General Policy on Expiry Checking

The medicines in the shelf of store, all retail areas, wards, critical care areas, OT etc. are checked once in every month for expiry date by the concerned staff responsible, the medicines are returned to the dealers 2 months prior to expiry date through pharmacy.

PROCEDURE (S)

The following policies have been established by the hospital to ensure an effective medication management system

- SDH/MOM/02 - Storage of Medications
- SDH/MOM/03 - Prescription of Medications
- SDH/MOM/06 - Medication Dispensing and Labeling
- SDH/MOM/08 - Medication Administration

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& Medication Management

- SDH/MOM/09 - Adverse Medication Events
- SDH/MOM/11 - Narcotics & Psychotropic Substances Handling
- SDH/MOM/05 - High risk medication
- SDH/MOM/12 - Chemotherapy Drugs
- SDH/MOM/13 - Radiotherapy drugs
- SDH/MOM/10 - Medication error
- SDH/MOM/04 - Verbal orders

Procedures have been established as a part of the Pharmacy Department Manual for defining and establishing a system for procurement, storage and dispensing of medications in the hospital;

- Procedure for Procurement of drugs
- Procedure for Central Pharmacy Operations
- Procedure for Retail Pharmacy Operations

The hospital has established separate policy and procedure for reporting and analysis of Adverse Drug Events.

MONITORING

The Drugs & Pharmacy Committee monitors the adherence to the medication management policy and processes across the hospital.

Individual Nursing Unit in-charges are responsible for monitoring of the implementation of the policies and procedures pertaining to medication management at the ground level on a day-to-day basis.


REFERENCES

Standards

MOM 1 – a, b

MOM 2 – a, b, c, d, e, f

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|--|-----------|--|-----------|
| Dr. Hrishikesh Kalgaonkar Chief Medical Administrator | | Dr. S.S. Deepak Chairman & Managing Director | |

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|---|--|----------|-------------|
|  | SAIDEEP HOSPITAL PHARMACY / MEDICATION USAGE MANUAL | Doc No | SDH/MOM/4.2 |
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| Document Title : Storage of Medications | | | |

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|---------------------|---|
| SUMMARY | <p>This document provides instruction and guidance to hospital staff on the medication storage in pharmacy and wards and other areas within the hospital and its protocols.</p> <p>All HODs throughout the hospital are required to instigate action to ensure the successful implementation of the policy within their area(s) of control.</p> |
| DISTRIBUTION | To all departments, units and wards through the Pharmacy & Medication Use Manual |

INTRODUCTION

An effective system of medication storage promotes patient safety. This is achieved through effective storage which ensures the quality and potency of medication. Effective storage also prevents the misuse of medication through defining effective security and access control measures to medications stored at the ward / unit level.

PURPOSE AND SCOPE

The purpose of this policy is to guide the hospital staff in the matter of storage of medication in their respective wards / units.

RESPONSIBILITIES

Chairman & Managing Director

The overall responsibility for implementing the policy rests with CMD of the hospital.


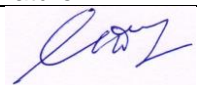
Chief Pharmacist


The Chief Pharmacist is responsible for ensuring the proper storage of medications at the pharmacies.

Nursing Superintendents and Ward Nurse In-Charges

They are responsible to ensure that the storage guidelines are followed at the unit level and periodically inspecting all medication storage (cupboards, crash carts etc.) to ensure compliance.

POLICIES

| Recommended By | Signature | Approved By | Signature |
|--|---|---|---|
| Dr. Hrishikesh Kalgaonkar Chief Medical Administrator |  | Dr. S.S. Deepak Chairman & Managing Director |  |

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Pharmacy Storage

The conditions and guidelines for medication storage in the various pharmacies are discussed in detail in the Pharmacy Services Manual. However the main points are discussed here too:

All drugs are arranged based on the alphabetical index of their brand names. Separate sections are allotted for different formulations like tablets/capsules, injections, suspensions and emulsions, ointments, pastes, jellies and creams, powders, suppositories and surgical sutures and ligatures.

Medications are stored in the racks of pharmacy based on their storage conditions mentioned in their label. Normal medicines are stored at room temperature.

Medications whose label suggest “store in cold condition” (2-8 degree Celsius) are stored in a refrigerator of which the temperature is maintained thermostatically between 2-8 degree Celsius.

Medications whose labels suggest “store in a cool place” (8-25 degree Celsius) are stored in pharmacy at the desired statutory temperature.

Vaccines where applicable shall be stored in Ice-Lined-Refrigerators.

Inventory Control


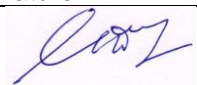
All narcotic drugs are stored in a locked locker whose key and stock is maintained by the person authorized by the head pharmacist.


All medications are protected from the free access of the public and secured with in various pharmacies. The medications are billed and dispensed based on the issue of valued prescription from a registered medical practitioner practicing in our hospital through counters.

All pharmacies follow a first in first out methods and separate batches are identified using a color coded labelling system to ensure FIFO

Chief pharmacist is responsible for the inventory control.

The medicines in the shelf of store, all retail areas, wards, critical care areas, OT etc. are checked once in every month for expiry date by the concerned staff responsible, the medicines are returned to the dealers 3 months prior to expiry through pharmacy.

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| Document Title : Storage of Medications | | | |

Physician Samples

Physician Samples are not allowed to be stored in pharmacies or in any in-patient clinical areas of the pharmacies. Physician samples received by the doctors in their OPD chambers are required to be taken home by them or donated for use by the charity wing of the hospital for free distribution in various medical camps and other such activities

Pest Control in Pharmacy

Medicines are arranged in steelslotted shelves and glass racks in plastic containers little above the flooring. Medicines are stored in dry and well ventilated areas.

Cold Chain Storage Breakdown Policy

1. Temperature reading of the refrigerator is monitored twice daily from the electronic device attached to the unit and noted.
2. If any variations in the temperature exceeds lower or higher limit, it is to inform to the engineering department for necessary action.
3. If the problem exceeds more than 4 hours, the items are shifted to the adjustment refrigerator or alternate spare refrigerator called for from the engineering department.
4. Calibration periods are promptly reviewed and necessary updates are done.

Ward / Unit Storage


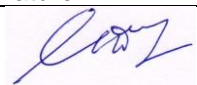
All medicines, and other substances issued by the Pharmacy department, shall be stored in the Wards and Departments in appropriate locked cupboards, with the exception of approved emergency crash trolleys for use in emergency situations. Approved emergency crash trolleys shall be clearly marked and be tamper-evident.


There should be separate storage for:

- Narcotics (only as per list of approved locations)
- Normal Medications (as per requirements of storage temperature including air conditioning)
- Medicines requiring Refrigeration

Patients' own medications will be stored at bedside trolley.

Each ward / department will maintain and display a list of medications to be stored in refrigerated storage. The guidelines for storage and handling of medications that need to be stored in a refrigerator are provided in pharmacy service manual.

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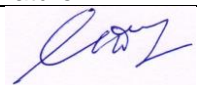
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| Document Title : Storage of Medications | | | |


Security

1. The custody of all drugs held in wards and pharmacy is the overall responsibility of the nurse in charge of that ward and the pharmacist.
2. The nurse in charge of a ward is responsible for controlling access to medicine cupboards, medicine refrigerators and emergency crash carts.
3. The keys of the medicines cupboard(s), crash cart(s) and drug refrigerator(s) are the responsibility of the nurse in charge of the ward and shall be held and passed on to shift in-charges assigned by the nurse in charge.
4. In any department / unit where staff does not include a nurse, the responsibility for the safe handling and storage of drugs shall be with the Unit In-Charge.
5. Medicines stored in wards and departments are for use in the treatment of patients in that ward or department and must not be given to patients to take away or be used by staff.

Control and Checking

1. It is the responsibility of nurse in charge to monitor the stock of medicines held in cupboards, refrigerators and emergency crash carts.
2. Medication Bottles / Containers / Packs with illegible or damaged labels must be returned to the Central Pharmacy for re-labeling or disposal.
3. Containers designated for multiple use (e.g. bottles of syrups / expectorants) etc. shall be labeled with date of opening. The same principle is applied for multi- use vials for injections (e.g. XYLOCAINE injections on dressing trolleys)
4. Pharmacy staff shall be given access to all medicine storage facilities and shall audit these once a month. A record of audit will be kept (both in the ward / department and in the pharmacy) with a note of any actions to be taken.
5. If a discrepancy in medicine stock is found, the procedure in an Incident Report must be initiated by the nurse in-charge as well as an "incident form" being completed and forwarded to the Quality Management Office.

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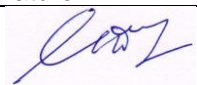
Emergency Crash Carts, Emergency Trays


1. A range of medicines is kept in Emergency / Crash Carts at each ward / identified units department for handling emergency situations / cardiac arrests / resuscitations.
2. The emergency crash cartis provided on all floors,provided in all ICUs and other locationsand will be maintained as per the checklist approved.
3. Emergency crash carts in the ICUs will be checked in the beginning of each nursing shift by the shift in-charge and initialed with time of checking in the check list which is hung on the side of each cart. In cases of units / departments where a nurse is not posted the technician in-charge will perform this check.
4. Emergency crash cart in the wards / non-ICU areas will be checked in the beginning of every month and sealed. They are replenished, checked and sealed after every use .
5. A list of locations / departments maintaining emergency crash carts will be available with Nursing Superintendent.

Sound Alike and Look Alike Drugs

1. As far as the look-alike &sound-alike drugs are concerned it is reported by the pharmacist whenever a new drug is added to the formulary to the chief pharmacist
2. The list is approved by the chief pharmacist, the display list is updated as and when the drug is included in the pharmacy formulary; it is displayed in all the pharmacies.
3. All units will maintain a list of Sound Alike and Look Alike Drugs which is maintained in their respective wards.
4. Look Alike and Sound Alike drugs are color separately color coded for their easy identification at all points of storage in the hospital
5. Such drugs are stored with clear separation from each other to avoid potential mix ups.

PROCEDURE (S)

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The Pharmacy procedure addresses the following issues pertaining to this policy; environmental conditions of storage, inventory control practices, prevention of loss and theft etc.


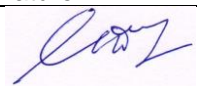
MONITORING

The Chief Pharmacist will conduct periodic inspections / audits of the ward stocks. The audit process will cover both the stock positions and adherence to storage guidelines. Reports of these audits will be forwarded to the MD.

REFERENCES

Standards

MOM 3 – a,b,,e,f,g

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| | | Issue No | 01 |
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| Document Title : Policies on Prescription and Ordering | | | |

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| SUMMARY | <p>This document provides instruction and guidance to Hospital staff on prescription and ordering of drugs and its protocols.</p> <p>All HODs throughout the hospital are required to initiate actions to ensure the successful implementation of the policy within their area(s) of control.</p> |
| DISTRIBUTION | To all departments, units and wards through the Hospital Manual |

INTRODUCTION

Effective system of medication ordering which is legible, standardized and followed universally within a hospital; reduces chances of medication errors and contributes to patient safety.

The NABH standards extensively cover the various aspects of prescription of medications and provide a baseline for the formulation of this policy.

PURPOSE AND SCOPE

The purpose of this policy is to guide the hospital staff in matters relating to prescriptions and medication ordering.

RESPONSIBILITIES

Chairman & Managing Director

The overall responsibility for implementing the policy rests with CMD of the hospital.


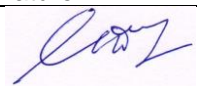
Clinicians

The clinicians are responsible for adhering to the prescription guidelines of the hospital.

Nurses

The nurses are responsible to ensure that they adhere to the guidelines provided by verbal and telephonic medication orders.

POLICIES

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| Document Title : Policies on Prescription and Ordering | | | |

A. Prescribing

All medicines (including medical gases) must be prescribed by a Duty Medical Officer/ Resident Medical Officer or above in the approved prescription area of the patient's medical record.

The people authorized to write a prescription include all the registered medical practitioners working in our hospital. Prescriptions are generally written on a typical format which is usually kept as pads in the respective departments.



The prescription must be written legibly (BLOCK CAPITAL LETTERS PREFERRED) and signed and dated by the authorized prescriber.

The generic drug name should preferably be used as far as possible, do not use any abbreviation and the prescription shall include the following:

- Hospital number.
- Date.
- Name, age and sex.
- Inscription.
 - **The approved name of the preparation**
 - **The dose**
 - **The frequency**
 - **The route of administration**
 - **Any other special instruction e.g. length of supply for courses**
 - **For children under 16 years – weight of the patient**
- Signature and designation of the prescriber.
- Error prone abbreviations shall not be used
- Errors / changes must be cut off with a single strike through, initialed and rewritten
- Drug allergies and previous drug reactions must be ascertained in each instance in point of care and prominently noted in prescription and medication order sheets

All prescriptions shall be made from the approved hospital formulary only.

All prescribing doctors must ensure that the prescription / medication orders are in consonance with good practices / guidelines for rational prescription of medications

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Electronic Prescription

Hospital has enabled electronic prescription / medication orders in both OP and IP modules of its HMIS. While it is not mandatory for physicians to use them currently, the hospital strongly encourages use of the same as it supports identification of drug reactions, food-drug interactions, therapeutic duplication, dose adjustment etc.

B. Doubts about Prescriptions

In accordance with professional responsibilities, any nurse or pharmacist who has **any doubt** about the prescription's legibility, accuracy or meaning **must not administer or dispense** the medicine and must notify the nurse in-charge immediately for verification with the prescriber.

Any alterations to a prescription must be in the form of a cancellation of the original instruction; the revised instructions being in the form of a new prescription. The cancellation should be clear and unambiguous, be signed and dated by the prescriber.

C. Verbal / telephonic Orders

Refer to Policy on Verbal Orders

D. Prescription Audit

The same is done on a sample sized and results analyzed on a monthly basis by a Clinical Pharmacist.


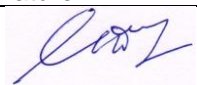
The findings of the audit is shared with the Drugs and Therapeutic Committee of their hospital.

Corrective / Preventive Actions are taken based on audit findings and are based on root cause analysis done where applicable.

Reconciliation of Medications at Transition Points

The reconciliation of medications are done by the nurses and RMO in the following manner

- Patient's existing medications are reviewed, documented and reconciled as a part of initial assessment process and a reviewed plan is implemented as per treatment plan by the primary / admitting physician

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- The primary / admitting physician reviews and reconciles medications at the time of receiving cross consultation referral inputs from physicians from other specialties.
- A medication reconciliation is documented as a part of patient hand over sheet from one ward / department to another
- The Primary Physicians with assistance of RMOs reconciles the medication prior to discharge to provide a comprehensive medication plan as a part of discharge advice and same is prescribed through the discharge summary

PROCEDURE (S)

The procedures / guidelines for Prescription of Medication are provided as an appendix to this policy.


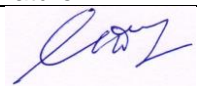
MONITORING

The CMA is responsible for monitoring the adherence to the policy.

References

A. Standards

MOM 4 – a, b, c,d,e,f,g,h

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Appendix 1. Guidance for Prescription & Medication Order Writing

In general all prescriptions must:

- be legible and indelible
- state the patient's full name, age, address and ward number / name
- state the treatment in block letters using the approved (generic) drug name
- state the form of the drug
- state the route of administration
- state the dose in the metric system
- state precisely the frequency and times of administration
- State the weight for children under 16 years.
- be signed with the prescriber's full signature
- be dated

These general requirements for prescriptions are expanded to more specific elements below:

ALLERGY



The allergy box on the inpatient drug chart / file must be completed before **ANY** medication can be prescribed.

DRUG NAME –

Approved drug must be written as the approved generic name (preferably) **without using abbreviations. When using brand names kindly ensure that only brands approved as per formulary are reused.**

DOSE –

- Specified dose is written appropriately on the prescription or in the appropriate box of the Drug Chart.
- Units must be written using acceptable abbreviations i.e. ml, g, and mg. The words units and micrograms must be written in full.

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- Dosages should be legible and unambiguous with no possible confusion over intended strength.
- Dose is written correctly, dose quantity must be written in words or Western Hindu Arabic numerals, using the minimum number of decimal places. Microgram doses should be used when appropriate.
- There should be no evidence of striking out or alteration of the dose.

ROUTE

- The intended route must be specified.
- The route must be legible and unambiguous.
- Use only acceptable abbreviations:

| | |
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| IV - intravenous | IM - intramuscular |
| SC - subcutaneous | PR - per rectum |
| TOP - topical | INH - inhalation |
| SL - sublingual | PV - per vagina |

- Oral and other routes should be written in full.
- Only one route should be specified (e.g. IM/ORAL, meaning intramuscular or oral, is unacceptable.)
- There should be no evidence of striking out or alteration of the route.

VALID PERIOD

Specified number of days for a course should be stated. Indication that the prescription is to be continued indefinitely is not acceptable.

FREQUENCY

- Legible and unambiguous: the frequency must be clearly defined. On ward drug charts this is done by entering specific times.
- The frequency must not be increased or reduced, without the entry being rewritten.
- Time of administration: the indicated time of administration has to be clearly stated. This applies to 'once only' prescriptions as well.

SIGNATURE

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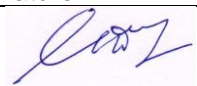
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The prescription / medication drug prescription must be signed by the prescriber in full signature with name.

DISCONTINUATION

Cancellation: to cancel a prescription, a line must be drawn through the prescribing section of the ward drug chart and the instruction signed and dated by the prescriber.

Alteration: if a drug is altered in any way, a line must be drawn through that section signed and dated by the doctor, and the drug rewritten with the alteration.

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| Document Title : Policies on Verbal Orders | | | |

| | |
|---------------------|---|
| SUMMARY | <p>This document provides instruction and guidance to Hospital staff on the policies of verbal orders and its protocols.</p> <p>All HODs throughout the hospital are required to initiate action to ensure the successful implementation of the policy within their area(s) of control.</p> |
| DISTRIBUTION | To all departments, units and wards through the Hospital Manual |

INTRODUCTION

Verbal orders are commonly used in the hospital scenario but can be a major source for medication related errors unless streamlined and standard processes for error reductions are not followed . Hence right checks and balances in this process level result in reduction of potential medication errors.

PURPOSE AND SCOPE

The purpose and scope of this policy are:


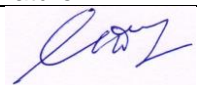
1. To ensure safety of medications when prescribed / ordered verbally by physicians
2. To ensure that any appropriate records are maintained when verbal orders are used.
3. To increase staff knowledge and understanding of verbal order process and as far as possible, develop an institutionalized approach to verbal orders.


POLICIES

Policies on Verbal / telephonic Orders

Instruction by telephone from a prescriber to a nurse to administer a medicine previously not prescribed is **unacceptable in normal circumstances**.

In exceptional circumstances where patient care could be compromised and where the medication has been previously prescribed and the authorized prescriber is unable to issue a new prescription,

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| Document Title : Policies on Verbal Orders | | | |

but where changes to the dose are considered necessary, a verbal order will be made to the duty medical officer manning the area.

This shall be recorded in the patient medical record. This shall be validated and countersigned by the prescriber within 24 hours.

In case of verbal orders the following process shall be adhered to;

A verbal order shall be issued only by anybody who is a Consultant or above that and none other than that. A seal is made available in the wards which shall be stamped and the verbal order given by the doctor shall be written down by the duty medical officer /duty nurse with the date, time, and whose order and the nurse signs it and then carries out the order.

The order once written down by the nurse shall follow this step of action also;

- The order shall be written and before closing the conversation (telephone or person) the **duty medical officer or duty nurse shall read back the order to the doctor** and confirm if the written down order is correct, in case of drugs she/he shall even spell the drug to recheck with the consultant and then close it.
- Doctor who issued the verbal order within 24 hrs should counter sign that verbal order, which was brought forward to the medication sheet by the Duty Medical Officer.


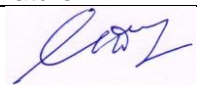
Verbal order – Not permitted

- Chemotherapy drugs are **high risk drugs**, Hence **Verbal orders are not permitted**
- Radioactive drugs are '**high risk drugs**', Hence **verbal orders are not permitted**
- Narcotics – **Legally not allowed**
- **High Alert Medications**

While administering these drugs verbal orders are not permitted. These drugs have to undergo the routine protocol of second check by a second person as according to high risk drug. (Details – chemotherapy and radiotherapy protocols)

STANDARD REFERENCE

MOM- 4 e

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| | | Rev No. | 01 |
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| Document Title : Policies on high risk medications | | | |

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| SUMMARY | This document provides instruction and guidance to Hospital staff on handling the high risk drugs and its protocols. All HODs throughout the hospital are required to initiate action to ensure the successful implementation of the policy within their area(s) of control. |
| DISTRIBUTION | To all departments, units and wards through the Pharmacy & Medication Use Manual |

INTRODUCTION

High Risk / A high Alert Medications carry a heightened risk for adverse ou

PURPOSE AND SCOPE

The purpose and scope of this policy are:

1. To ensure that patients are administered prescribed medications safely.
2. To ensure that appropriate records are maintained.
3. To increase staff knowledge and understanding of medication management process and as far as possible, develop an institutionalized approach to medicines' administration.

RESPONSIBILITIES

Chairman & Managing Director


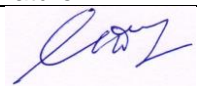
The overall responsibility for implementing the policy rests with CMD of the hospital.

Nursing Staff

The nurses are responsible for implementing the provisions of this policy.

Policies of hospital for administering high risk medicines are:

- High risk medication orders are verified with regards to patient name, diagnosis, ordering doctors, dose and route, frequency of administration.

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|  SAIDEEP <small>HEALTHCARE & RESEARCH PVT. LTD.</small> | SAIDEEP HOSPITAL PHARMACY MEDICATION MANAGEMENT MANUAL | Doc No | SDH/MOM/4.5 |
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- Patients are instructed regarding the likely adverse events in a manner which doesn't produce apprehension.
- Patients are observed for a specified period of time for adverse events and hemodynamic responses.


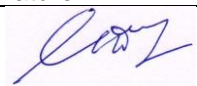
The high risk medications used in our hospital are listed, updated and published by the Drugs & Therapeutics Committee and displayed prominently in all the patient care areas. All staff are trained on the listed medications as a part of Medication Management in services training

While administering these drugs the following has to be done;

1. A second check by a second person will be required for all 'High Risk' medications and things to be checked are,
 - a) Medication chart for the order
 - b) Correct product
 - c) Dose
 - d) Calculation
 - e) The initial set up of the infusion device
 - f) Chamber shall be clearly labeled with medication infusing

If there is a question or doubt regarding the drug, dosage, concentration, or calculation, consults the doctor.

2. Assistance in calculations, including dosage charts, weight charts, and preprogrammed infusion pumps, and clear labeling on the dispensed dose will promote medication safety.
3. A double check of all doses and calculations is needed prior to administration of the above high risk medications.
4. Two individuals should independently check calculations of high-risk drugs.
5. The double check should include the chart order, the calculated dose and the pump infusion.
6. Double check that the correct product is selected (and the correct concentration) and double check the dose drawn up. (In case of IV injections)
7. For infusions via controlled infusion devices (example: IV potassium, heparin, dopamine, etc.):
 - Double check that the correct product is selected (and the correct concentration)
 - Double check the initial set up of the infusion device
 - A double check is needed if there is an addition/deletion of one of the additives

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- A change in concentration/strength (double/quad)

8. The chamber shall be clearly labeled with medication infusing.


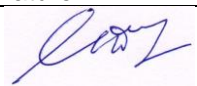
WHO CAN PERFORM A DOUBLE CHECK?


- Registered nurses
- Paramedics
- Pharmacist

For high risk medications at least two nurses should verify all administration related parameters and checks before administrations. In an emergency situations like resuscitation the administrating clinician or nurse will call out the name, dose and mode for the benefit of the other members of the code team and the team leader will verbally confirm to avoid any errors.

STANDARD REFERENCE

MOM-4 c. d, e

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| | | Issue No | 01 |
| | | Rev No. | 01 |
| | | Date | 1 Nov 21 |
| | | Pages | 1 |
| Document Title : Policies on Medication Dispensing | | | |

| | |
|---------------------|--|
| SUMMARY | <p>This document provides instruction and guidance to Hospital staff on medication dispensing issues and its protocols.</p> <p>All HODs throughout the hospital are required to initiate action to ensure the successful implementation of the policy within their area(s) of control.</p> |
| DISTRIBUTION | To all departments, units and wards through the Pharmacy & Medication Use Manual |

INTRODUCTION

Safe and Sound dispensing practice include requisite verifications and check of dispensed medications in terms of routes, strengths , expiry etc. ; coupled with dispensing advice from the health service providers.

PURPOSE AND SCOPE

- The policy document discusses the requirements of the NABH standards pertaining to dispensing and labelling of medications and its application and implementation in the Hospital.
- The policy is applicable to all units of the hospital.

RESPONSIBILITIES


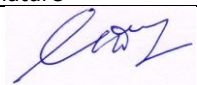
Medical Director.


The overall responsibility for implementing the policy rests with Chief Medical Administrator of the hospital.

Pharmacists & Nurses

The dispensing pharmacists and nurses in the wards are responsible to ensure that dispensing and labeling standards are followed.

POLICIES

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A. Dispensing to Out Patients

The dispensing of medicines for outpatients through retail pharmacy is detailed in the Pharmacy Services Procedure

The method adopted by the retail pharmacy outlets in dispensing the drugs includes:

- Receiving the prescription on the basis of the queue.
- Billing the prescription.
- Issue of token on cash payment.
- Retrieving the medicine on the basis of the bill.
- Checking the medications retrieved on the basis of the prescription.
- Calling the token and
- issuing the drugs
- Explaining to the patient regarding the drug intake, dos and don'ts etc.

B. Indent from Wards

The nurse in charge of the Ward is responsible for the indent of medicines for that Ward or Department from the Central Pharmacy.

Medicines for ward or departmental stock are supplied by pharmacy staff operating the Issue Counter at the Central Pharmacy.


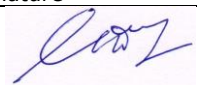
The indent of medicines for the wards requires the following information:


- Hospital, Ward name
- Date
- Code number of the indenting material with details of existing stock and quantity required
- Name of medicine including dose, strength and quantity
- Name of the Ward Supervisor who is indenting

Issue of the drugs from the pharmacy store to the wards, critical care areas, OT etc. is done twice, every month based on the corresponding indent.

The entry can be done by a staff nurse and the approval is done by the ward supervisor after verification.

This information goes directly to the pharmacy and the drugs are issued.

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C. Indent for Inpatients

The bystanders shall purchase the medicines based on the prescription given.
The purchased medicines are given to the nurse of the ward who shall administer it
To the patient. Patient self-medication is not allowed.

D. Drug replacement and inpatient

Medicines for inpatient in wards and for the drug replacement in places like critical care areas are supplied by the pharmacy.

The requirement of such medicines requires the following information.

- Hospital, Ward and unit Name
- Date & Time
- Patient name and hospital number
- Name of medicine including dose, strength and quantity
- Name and signature of the doctor

E. Delivery and Receipt

Medicines are transported to Wards and Departments in sealed tamper-evident packages/boxes/PTS by approved messengers. The sealed package must be signed for in the delivery record book by a registered nurse upon receipt in the ward /department.


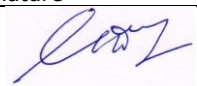
In case where the ward nursing staff are collecting the weekly issues for replenishment of ward stock the collecting nurse will sign for the issue in the issue register maintained at the issue counter in the central pharmacy.

Failure to receive medicines ordered or discrepancies in medicines received must be notified to the Central Pharmacy Immediately.

F. Documents and Records

Prescription forms, Requisition Books, Narcotics Order Books and Record Books must be kept in a secure place with access only to designated personnel.

G. Labeling Requirements

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- All labelling of items removed from their original container/package occurs at the time the medication is being prepared, even if there is only one medication being prepared. Use of pre-labelled packaging from the manufacturer is unacceptable.
- Any unlabelled or partially labelled medication or solution is discarded immediately.
- Label one medication at a time (e.g., Get the first medication and label per guidelines, then get the second medication and label per guidelines, etc.
- All labels are verified both verbally and visually by two qualified individuals when the person preparing the medication is not the person administering the medication.
- Upon a shift change or break relief (change in personnel involved with labelled medications, such as in the operating room or procedural areas), all medications/solutions and their labels are reviewed by entering and exiting persons.
- Attaching the original container (vial/amp, etc.) to the final container is unacceptable.

PROCEDURE (S)

The dispensing procedures are also described in the Pharmacy Services procedure.

MONITORING

The medical superintendent is responsible for monitoring of the process.

REFERENCES

- A.
- B. Standards

MOM 6 - a,b,c,d,e,f

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| Doc No | SDH/MOM/4.7 |
| Issue No | 01 |
| Rev No. | 01 |
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| Pages | 1 |

Document Title : Policies on patient own medications

| | |
|---------------------|---|
| SUMMARY | This document provides instruction and guidance to Hospital staff on intake of patient's own medications and its protocols. All HODs throughout the hospital are required to initiate action to ensure the successful implementation of the policy within their area(s) of control. |
| DISTRIBUTION | To all departments, units and wards through the Hospital Manual |

INTRODUCTION

Patients' own medication is a key issue that can lead to medication errors. Most patients especially senior citizens are likely to be under regular medications for Chronic conditions like diabetes, blood pressure related conditions, cardiac problems etc.

These medications have potential to react with medication prescribed by the hospital or cause adverse physiological events detrimental to treatment lines undertaken in the hospital. Hence processes have to be established as a part of medication management system to address the issues.

PURPOSE AND SCOPE

The purpose and scope of this policy are to:

1. To ensure that existing medications taken by the patient is accounted for as part of the patients assessment.
2. To ensure that no unauthorized drugs are brought to the hospital from outside sources; so that the hospital can ensure the quality of all medications.

RESPONSIBILITIES

Chairman and Managing Director

The overall responsibility for implementing the policy rests with Medical Director of the hospital.

Nursing Staff

The nurses are responsible for implementing the provisions of this policy.

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| Chief Medical Administrator | | Chairman & Managing Director | |



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Document Title : Policies on patient own medications

POLICIES

A. Medicines Brought into Hospital by Patients (Patients' Own Medication)

- Hospital inpatients shall be advised of the need to inform staff of medicines they are currently taking and have brought into hospital.
- This statement shall be included in the patients' rights & responsibility / patients' information booklets.
- All medicines brought in by patients are their property and the patient's consent (verbal) for their removal or use must be obtained.
- Inpatient - Self administration not permitted.
- Patients who have been on regular medicine for some other diseases/ailments are continued. These medicines are written on order-sheet by doctors and dispensed to the patient by staff.
- It is the hospital's policy to ask patients to bring their current medication with them on admission. This enables staff to see what treatment the patient is having and allows accurate medication history taking.
- The residents serving in their units will decide on continuation of the current medications. The list of current medication to be continued will be written on the patient chart as a medication order with appropriate details.
- The nursing staff will then include the patient's current medications as a part of the medication administration plan.
- Drugs which are no longer needed or which may be detrimental to the patient's treatment should, with the patient's consent, be disposed of or sent back with the patient attendants. In no case the unwanted medication should be allowed to mix with the patient's medication increasing chances of medication errors.

MONITORING

The respective nursing in-charges of each ward are responsible to monitor the adherence to the policy by nurses.

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| Chief Medical Administrator | | Chairman & Managing Director | |



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Document Title : Policies on patient own medications

REFERENCES

- A. Standards
MOM 7-k



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| Document Title : Policies on Medication administration | | | |

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| SUMMARY | <p>This document provides instruction and guidance to Hospital staff on medication administration and its protocols.</p> <p>All HODs throughout the hospital are required to initiate action to ensure the successful implementation of the policy within their area(s) of control.</p> |
| DISTRIBUTION | To all departments, units and wards through the Pharmacy and Medication Use Manual |

INTRODUCTION

Medication administration processes are the key stone to reducing medication errors in the hospitals. Actual administration of medication is the terminal event in a process chain of the medication management cycle. Hence right checks and balances in this process level result in reduction of potential medication errors.

PURPOSE AND SCOPE

The purpose and scope of this policy are to:

1. To ensure that patients are administered prescribed medications safely.
2. To ensure that any appropriate records are maintained.
3. To increase staff knowledge and understanding of medication management process and as far as possible, develop an institutionalized approach to medicines administration.

RESPONSIBILITIES


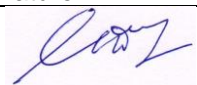
Medical Director.

The overall responsibility for implementing the policy rests with Medical Director of the hospital.

Nursing Staff

The nurses are responsible for implementing the provisions of this policy.

POLICIES

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A. Administration of Medicines

Only qualified medical and nursing staffs are allowed to administer medication to patients. Whereas during special situation the designated person shall administer the following:

- Chemotherapeutic agents - Doctors/Chemotherapy Nurses
- Injectable - Senior staff nurses.
- Oral Medicines – Staff nurses / ANMs (In General Wards)
- Blood transfusion – Doctors / Nurses
- Implants by the concerned surgeons after proper informed consent by the patient or relatives

Nursing trainees involved in medication administration will perform the same under supervision of staff nurses.

Medicines shall only be administered in accordance with a prescription or agreed protocols.

Doctors will explain to the patient regarding the type of food intake and food to be avoided during a particular drug intake. Consultant while taking rounds shall explain the risks involved in the particular drug, on his/her absence another doctor deputed by him/her shall do the same.

Self Administration of Medication

The hospital does not allow self-administration medications by the patients including self-administered insulin.

PROCEDURE (S)


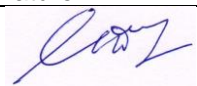
Procedure for Administration of Medicines

A. Responsibilities of Administration

The administration of medicines, including medical gases and intravenous fluids will be undertaken by either:

- I) A qualified nurse posted in the ward / department.
- II) A duty medical officer and registrar posted in the ward / department

B. Second Person Reviews

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It is recognized that there are situations where a second person may be required and this need should be assessed by the nurse who is responsible for the administration. Such situations may be due to the status of the patient or where a drug dose needs calculation. The following specific situations require a second person whatever the circumstances.

1. Narcotics
2. Where a calculation of dose is required
3. Administration to children under 12 years of age
4. Where a drug dose is weight related
5. Intravenous drugs

Drugs must be prepared by the person who is to administer them and they must be given immediately after preparation. In case of multi-dose vials, the remaining dose should be stored in appropriate conditions approved by the DTC. The nurse is responsible for ensuring that the form of the drug is appropriate for the route of administration.

C. Safeguards in Medication Administration


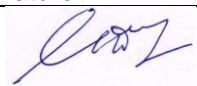
The following points must be checked by the administering nurse:

- Patient's name on prescription sheet
- Prescription sheet is clearly written and signed by the prescriber.
- The prescribed time, date and method of administration
- The drug name on the container is the same as that on the prescription / order sheet.
- Check allergy box is completed and patient is not allergic to the medication prescribed.
- The dose has not already been given
- The correct dose of the drug is prepared
- The identity of the patient, with reference to the MRN (in wards where it is used)

IF THERE IS ANY DOUBT REGARDING THE ABOVE, THE NURSE MUST REFER THE MATTER BACK TO THE PRESCRIBER

| | |
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| ALWAYS ENSURE | |
| RIGHT | <u>Patient</u> <u>Medication</u> <u>Dosage</u> <u>Route</u> <u>Timing</u> |

D. High Risk Medications

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(Details – refer to high risk medication policy)

Each nursing unit will list and prominently display the list of high risk medications. The list of high risk medications will be approved by the Drugs & Therapeutic Committee and reviewed on a yearly basis.

For high risk medications at least two nurses should verify all administration related parameters and checks before administrations. In emergency situations like resuscitation the administering clinician or nurse will call out the name, dose and mode for the benefit of the other members of the code team and the team leader will verbally confirm to avoid any errors.

E. Self Administration of Medication

The hospital does not allow self administration of medications. All medications including insulin have to be ADMINISTERED by a nurse.

F. Recording

The administration of the drug must be recorded on the drug chart after administration has occurred and been observed.

If a prescribed drug is not given, the reasons for omission must be recorded on the case sheet.


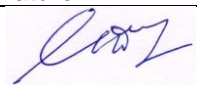
MONITORING


The respective nursing in-charges of each ward are responsible to monitor the adherence to the policy by nurses.

REFERENCES

Standards

MOM 7 – a,b,c,d,e,f,g,l,j

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| | | Date | 1 Nov 21 |
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| Document Title : Policies on Adverse Drug Events / Reactions | | | |

| | |
|---------------------|--|
| SUMMARY | This document provides instruction and guidance to Hospital staff on handling the adverse drug reaction and its protocols. All HODs throughout the hospital are required to initiate action to ensure the successful implementation of the policy within their area(s) of control. |
| DISTRIBUTION | To all departments, units and wards through the Pharmacy & Medication Services Manual |

PURPOSE

To readily identify patients with known food, drug and environmental allergies/adverse drug reactions and to provide for documentation of such on the Patient Assessment, in order to prevent the possibility of reactions.


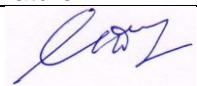
DEFINITIONS


1. Allergy - a disease or reaction caused by an immune response to a drug, resulting in tissue inflammation and/or organ dysfunction usually, but not always, characterized by angioedema, rash or anaphylaxis.
2. Adverse Drug Reaction (ADR) - any response to a drug which is noxious and unintended and which occurs at doses normally used in humans for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.

POLICY

1. A history of any allergies/ADRs shall be obtained during the admission nursing assessment before any medications are administered, except in emergencies. This history is documented in the space provided on the Patient History/Assessment and Discharge Record.
2. Suspected Adverse Drug Reactions shall be identified and reported on the **Patient Incident Form**, which is available at all Nursing Units. The filled up forms should reach the Quality Manager on the same day for analysis. The physician must also document the ADR in the Progress Notes of the patient's medical record.
3. The Drugs & Therapeutic Committee will be responsible for monitoring of reported adverse reactions. All severity level 5 and 6 reports shall be forwarded to the QPS office for Root Cause Analysis.

Allergic Idiosyncratic Irritant Pharmacologic Severity Scale

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- Level 1 – ADR occurred but required no change in treatment with suspected drug
Level 2 – Drug held, discontinued or changed but no antidote or additional treatment needed.
Level 3 – Drug held, discontinued or changed AND/OR antidote or other treatment required.
Level 4 – ADR required patient transfer to an intensive care setting
Level 5 – ADR caused permanent harm to the patient
Level 6 – ADR either directly or indirectly led to the patient’s death

The reaction will be reported to the manufacturer or the Drug Controller of India if:

1. The ADR is classified probable or definite and is a severe reaction.
2. The ADR is probable or definite and is not listed in the manufacturer’s package insert.
3. The ADR involved is a new drug (released in the last three years) and exhibits a temporal relationship to the administration of the new drug.

Root Cause Analysis is done where applicable and records of same maintained.

The DTC ensures appropriate Corrective and Preventive Actions are taken based on the analysis and records of same are maintained.

MONITORING

The Pharmacy & Therapeutic Committee will be responsible for monitoring all ADR / ADE and conduct analysis. The Severity V and VI reactions are monitored by CMA / CMD directly on an immediate basis.


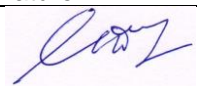
REFERENCES

STANDARDS

MOM 8 – c,d,e,f

Other Policies & Manuals

Policy on Incident Reporting

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| Chief Medical Administrator | | Chairman & Managing Director | |

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| | | Issue No | 01 |
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| Document Title : Policies on Medication errors | | | |

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| SUMMARY | <p>This document provides instruction and guidance to Hospital staff on Medication errors and its protocols.</p> <p>All HODs throughout the hospital are required to instigate action to ensure the successful implementation of the policy within their area(s) of control.</p> |
| DISTRIBUTION | To all departments, units and wards through the Pharmacy & Medication Management Manual |

PURPOSE

The purpose is to identify and report the medication error in patients. To provide for documentation of such in the incident form, preventing reoccurrence of the same and to identify training needed if any.

SCOPE



Pharmacy and all patient care units

DEFINITIONS

Medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems including: prescribing; order communication; product labelling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

Types of Medication Errors

1. Wrong Prescription i.e. incorrect dose, route, frequency, drug name, and illegible order
2. Indent error i.e. wrong drug, strength, dose, route, frequency
3. Dispensing delay of >2 hours, wrong drug, strength
4. Administration errors:
 - a. Wrong time
 - b. Wrong patient
 - c. Wrong medication

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- d. Wrong dose
- e. Wrong route
- f. Wrong documentation

Major medication error is one which results in either permanent harm or transfer to the intensive care units or death.

POLICY

1. When an error is identified, it shall be reported on an “incident form” to nurse in charge and the doctor on duty immediately.
2. Reporting an error must be part of the ordinary routine, and simple to do. It must also be non-punitive so that staff does not have to be afraid of repercussions.
3. An error shall be reported to the concerned consultant immediately.
4. Continuous monitoring and frequent assessments shall be done for the patient
5. An incident form shall be filled up with signatures of both the doctor and nurse. The Nursing Supervisor shall send this to QM Office.
6. The QCO shall maintain the incident database. The database shall be forwarded to the Quality Team on a monthly basis. The data shall be reviewed by the Drug Committee on a quarterly basis.
7. A Root Cause Analysis (RCA) shall be done for all major medication errors.



MONITORING


The QM will be responsible for monitoring all medication errors, ADR / ADE and conduct Root Cause Analysis.

REFERENCES

Standards

MOM 8-c,d,e,f

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| | | Date | 1 Nov 21 |
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| Document Title : Narcotics Handling Policy & Procedures | | | |

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|---------------------|---|
| SUMMARY | This document provides instruction and guidance to Hospital staff on handling the narcotic drugs and its protocols. All HODs throughout the hospital are required to instigate action to ensure the successful implementation of the policy within their area(s) of control. |
| DISTRIBUTION | To all departments, units and wards through the Pharmacy and Medication Management Manual |

INTRODUCTION

Narcotics and Psychotropic Substances Act covers the use of some vital drugs like Pethidine, Morphine and Fentanyl etc. which are regularly used in a tertiary care center involving large number of surgical and critical care patients.

However due to high potential of abuse of these substances; government has established strict licensing terms for their use by the approved medical institutions. Violations of these licensing can lead to criminal proceeding against the licensee in case of violations both by commission or omission.

PURPOSE AND SCOPE

The purpose and scope of this policy are to:

1. To ensure that terms of license awarded to the hospital under the Narcotics and Psychotropic Substances Act are adhered.
2. To define the roles and responsibilities of persons to whom the rights to issues, administer and monitor such medications are assigned.
3. To increase staff knowledge and understanding of the rules and processes governing this class of medications.


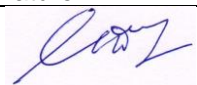
RESPONSIBILITIES


Chairman & Managing Director

The overall responsibility for implementing the policy rests with CMD of the hospital.

Pharmacy & Nursing Staff

The assigned pharmacists and nurses are responsible for implementing the provisions of this policy.

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POLICIES

Narcotics must be handled in accordance with the Narcotics and Pyschotropic Substances Act, Rules and Regulation of the license.

PROCEDURE

Procedure for Management Narcotics

a. Storage

All Narcotics must be stored in separate cupboard under lock and key maintained by persons approved by the Medical Superintendent.

The current locations in the hospital approved for stocking with list of approved personnel for handling and stock level to be maintained are as follows;


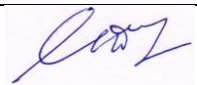
Narcotic drugs permitted in our hospital are:


- Inj. Morphine
- Inj. Fentanyl
- Inj. Pentazocin

| No. | LOCATIONS | DRUGS | NUMBER PERMITTED | INCHARGE | DESIGNATION |
|-----|-------------|--------------------------------|------------------|-----------------|--------------|
| 1. | Pharmacy | Morphine, Fentanyl, Pentazocin | 100 each | Head Pharmacist | Pharmacist |
| 2. | Casualty | Pentazocin | 5 | | |
| 3. | ICU | Morphine, Fentanyl, Pentazocin | 5 each | RMO | RMO |
| 4. | OT | Morphine, Fentanyl, Pentazocin | 5 each | Anaesthetist | Anaesthetist |
| 5. | Wards | Not allowed | None | | |
| 6. | Labour room | Morphine | 5 | Anaesthetist | Anaesthetist |

B. Accountability and Responsibility

A pharmacist or Nursing Staff is nominated as authorized personnel at all location of Narcotics stocking. The authorized personnel can delegate control of access (i.e. key-holding) to the Narcotic

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Locker / cupboard to another registered nurse / pharmacist of the same unit (for ensuring access through the various shifts). However, legal responsibility remains with the authorized person. Whilst the task can be delegated, the responsibility cannot. The keys of the Narcotic cupboard shall be kept separately from other keys.

c. Ordering

Only medical personnel attached and privileged with hospital are permitted to order Narcotics. Narcotics must only be ordered in the ward drug / prescription chart only. A separate page must be used for each drug. Each order must be in indelible ink and state:

- Hospital, Ward or Unit name
- Date
- Name and form of the preparation
- Strength and quantity required
- The printed name and qualifications of the signatory

Narcotics can be requisitioned from the main stock at the pharmacy by the sub stock units through a separate requisition slip signed by the authorized personnel for that stock unit and the HOD of the department. Requisition for Narcotics will not be mixed with requisition of other drugs.

The sub-stock book maintained will be sent to the pharmacy for verification of the stock.


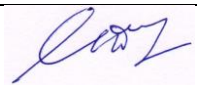
Used vials of consumed stock will be returned along with the requisition for new stock.


d. Delivery and Receipt

Narcotics are delivered to wards by an approved messenger in a sealed tamper-evident package/PTS. The package will be accompanied by a Narcotic Delivery record sheet, which must be signed on receipt in the ward by an authorized person and returned to the HOD Pharmacy. On no account should Narcotics or its used vials be left unattended.

Receipt of a Narcotic should only be by the authorized person of that ward/ department.

When the contents do not match the expected amount stated on the pack, the authorized(person) in charge should contact the chief pharmacist. Appropriate records should be made in the Narcotic register and all necessary action taken to resolve the discrepancy. The Medical superintendent/associate director will be informed immediately in writing and a separate incident form filed to the Quality Coordinator.

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Under **no** circumstances can entries in the Main or Ward Narcotic Stock Register be altered, erased or obliterated. Any entry made in error in the Main or Ward Narcotics Stock Register is to be annotated as “entered in error” and signed by both the authorized personnel for the ward and HOD of that Department. In case of the main stock register the changes should be countersigned by the Medical Superintendent.

e. Control and Checking

Narcotics must be checked at least weekly. This should be organized by and is the responsibility of the authorized persons in charge of the ward /department.

The Ward Narcotics Stock Register shall be kept in a locked cupboard.

Pharmacy staff (approved personnel) shall be given access to all storage facilities and shall inspect these every month. A record of inspections will be documented with a note of any actions taken.

f. Records and Documents

It is unlawful to obliterate or erase an entry in the Narcotic related Registers because it must remain legible, even if made in error.

Each page is numbered and **must not be removed**.

Narcotic Order Books and Registers must be kept in a secure place with access only TO designated personnel (ideally inside the stored cupboards).


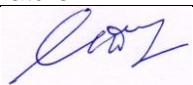
All documents and records must be retained in the relevant ward / department for a period of two years from the date of the last entry. Then, the records must be destroyed by shredding.


g. Prescribing

As per guidance for prescription

h. Administration

In hospital the administration of Narcotics must be carried out by qualified nurse or Duty Medical Officer. Students and trainees shall not administer Narcotics.

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The following guidelines should be followed at the time of administration

When removing the Narcotic from the cupboard:


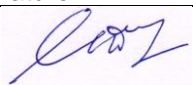
- Two persons must check the label against the prescription.
- Two persons must check the amount left in stock against the balance in the Ward Narcotic Stock Register.
- **If the prescribed dose is only part of an ampoule, the unused part must be discarded immediately, by one of the persons in the presence of the other. The amounts given and wasted must be entered in the register and signed by BOTH persons.**
- The entire process, from removal of the drug from the cupboard to its administration to the patient must be carried out by **two persons**.
- Individual doses of Narcotic which have been prepared but not administered should be destroyed in the ward/department by a registered nurse in the presence of a witness. The reason should be documented in the Narcotic Stock Register.
- If a mistake is made in the register it should be bracketed in such a way that the original entry is still clearly legible. This should be signed, dated and witnessed by HOD (for ward stock)


i. Incidents involving Narcotics

When a Narcotic discrepancy is found on a ward /department, in the first instance the following should be carefully checked-

- All requisitions received have been entered onto the correct page of the register
- All Narcotics administered have been entered into the register
- Items have not been put in the wrong place in the cupboard
- Arithmetic to ensure that balances have been calculated correctly

If the error is traced, the authorized person in charge should make an entry in the register clearly stating the reason and the corrected balance. This should be validated by HOD in case of wards and Medical superintendent for the main stock at Pharmacy.

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If the error cannot be detected then the Medical superintendent/associate director would be intimated immediately in writing and an '**incident reporting form**' initiated and sent to QCO.

All Narcotic incidents are automatically categorized "Moderate", "Major" or "Catastrophic" and so there will be an investigation and a root cause analysis by a multidisciplinary team

j. Returning Narcotics to the Pharmacy

Narcotics that are time –expired or unfit for use should be returned to pharmacy for disposal.

Narcotics are returned by the approved person for the ward who will make the entry in the relevant page of the Narcotics Stock register and have this validated by the HOD. A record of any drugs returned (and any further transactions e.g. disposal or return to authorized supplier) is kept in the central pharmacy.


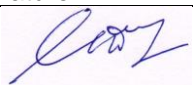
MONITORING


The Chief Pharmacist and Medical superintendent/associate director are responsible for monitoring the implementation of this policy.

REFERENCES

Standards

MOM 9 – a,b,c,e

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| Document Title : Policies on chemotherapy drugs | | | |

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| SUMMARY | This document provides instruction and guidance to Hospital staff on handling the chemotherapy drugs and its protocols. The HOD concerned of the hospital is required to initiate action to ensure the successful implementation of the policy within their area(s) of control. |
| DISTRIBUTION | To all departments, units and wards through the Pharmacy & Medication Management |

INTRODUCTION

Chemotherapy drugs is a vital category of high risk medication handled in a hospital and requires specialized arrangements and process to handle them by trained personnel for their own safety and safe administration for patients.

PURPOSE AND SCOPE

The purpose and scope of this policy are to:

1. To ensure that chemotherapy medications are prescribed, prepared and administered safely.
2. To ensure that any appropriate records are maintained.
3. To increase staff knowledge and understanding of chemotherapy medication handling process and as far as possible, develop an institutionalized approach for same

RESPONSIBILITIES

Chairman and Managing Director



The overall responsibility for implementing the policy rests with Medical Director of the hospital.


Nursing Staff

The nurses are responsible for implementing the provisions of this policy.

HOD ONCOLOGY

It is the responsibility of the HOD oncology to implement these policies in his/her department.

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The personnel permitted to administer a chemotherapy drug to the patient (IP) in our institution are Doctors /House surgeons / Staff nurse

Administration of chemotherapy drug to the patient is based on the doctor's prescription. The drugs are administered by experienced staff nurses under the supervision of the head nurse.

The direction for drug administration in the prescription is strictly followed which includes:

- Preliminary physical check-up. (general condition)
- Whole blood test.
- Vital signs.

Necessary precautions are taken which includes administration of pre-medications, monitoring; followed by administration of the chemotherapeutic drug checking the patient's vital signs.

In case of any adverse drug reactions the administration of drug is stopped and reported to the Doctor.

The patient is monitored for one hour before sending to room/discharge.

Chemotherapy drugs are also **high risk drugs** hence

Verbal orders are not permitted and



Additionally while administering these drugs the following has to be done;


1. A second check by a second person will be required for all "high risk "Medications and things to be checked are,

- a) Medication chart for the order
- b) Correct product
- c) Dose
- d) Calculation
- e) The initial set up of the infusion device
- f) Chamber shall be clearly labeled with medication infusing

If there is a question or doubt regarding the drug, dosage, concentration, or calculation, consults the doctor.

2. Assistance in calculations, including dosage charts, weight charts, and pre-programmed infusion pumps, and clear labeling on the dispensed dose will promote medication safety.

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3. A double check of all doses and calculations is needed prior to administration of the above high risk medications.

4. Two individuals should independently check calculations of high-risk drugs.

5. The double check should include the chart order, the calculated dose and the pump infusion.

6. Double check that the correct product is selected (and the correct concentration) and double check the dose drawn up. (In case of IV injections)

7. for infusions via controlled infusion devices:

- Double check that the correct product is selected (and the correct concentration)
- Double check the initial set up of the infusion device
- A double check is needed if there is an addition/deletion of one of the additives
- A change in concentration/strength (double/quad)

8. The chamber shall be clearly labeled with medication infusing.



WHO CAN PERFORM A DOUBLE CHECK:


- Registered nurses
- Paramedics
- Pharmacist

For high risk medications at least two nurses should verify all administration related parameters and checks before administrations. In emergency situations like resuscitation the administrating clinician or nurse will call out the name, dose and mode for the benefit of the other members of the code team and the team leader will verbally confirm to avoid any errors.

STANDARD REFERENCE

MOM 9 – a,b,c,d,e

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| Document Title : Policies on Implantable prosthesis and medical devices | | | |

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| SUMMARY | This document provides instruction and guidance to Hospital staff on handling the implantable prosthesis and its protocols. All HODs throughout the hospital are required to initiate action to ensure the successful implementation of the policy within their area(s) of control. |
| DISTRIBUTION | To all departments, units and wards through the Hospital Manual |

INTRODUCTION

Several of the super specialty departments like Orthopedics and Cardiology uses implantable prosthesis and devices like joints, pace makers etc.

It is important to maintain the systematic records of these devices for the benefit of the patients and to ensure continuity of care and also to tackle future issues of malfunctions.


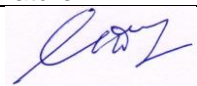
POLICIES


1. Hospital uses various manufacturers of implants as approved by the purchase In-charge in consultation with respective HODs. These implants are 8-9 varieties, manufactured by different companies. The implants to be used in particular patient are selected by the concerned unit head / surgeon / physician in discussion with the patients and family after explaining the benefits and side effects of the same. Two methods are adopted. One, the implants are directly ordered from the OT by the OT staff. Two, an order is placed to the purchase department after the consent of the HOD through the Purchase In-charge. In patients with poor economic condition, to reduce the cost of surgery, locally manufactured implants are used after explaining to the patient.

2. All purchases of the implants and devices follow the purchase policies of the hospital.

The commonly used implants can be kept in hospital pharmacy after following the quotation system as used for the medications. The doctors concerned can give the list of implants required and those with best rates (to patient and to Saideep Hospital & Research Pvt. Ltd. may be selected as being done for antibiotics and other medications.

Orders can be placed through the pharmacy for commonly used prosthesis, and a few of them may be kept in the OT / procedure room as is being done for drains/surgical/VP shunts etc.

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3. All the implants are held in hospital operation theater medical stores and replacement order is placed with the same company supplying the implants.

4. Selection of specific type of implant depends on:

- a. Patients' decision based on economic condition.
- b. The deformity, its type and severity, a patient has.
- c. Type and pattern and extent of fracture.
- d. Surgeons' choice

This policy will work in tandem with the policy and procedures for consignment items in the hospital purchase manual.

The departments where prosthesis is used are Orthopedic, Urology, Oncology, Neurology, Cardiology and ENT.

The method of procuring prosthesis for different departments includes:

- Orthopedic/Neurology - Order directly placed to the stockist instantly based on the operations posted.
- Urology/Oncology - Through pharmacy.
- Cardiology - Order directly placed to the stockist instantly based on the operations posted.
- ENT - Through the central store of the hospital.


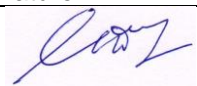
5. The billing to the patient is done according to the type of implant used.


6. Similarly for all trauma / orthopedic cases needing plating, wiring and fixation by screws, indigenous and foreign material is used based on patients; or surgeons; choice and type of injury sustained by the patient

7. Almost all types of implants used in trauma cases are readily available in the hospital medical store; some specific implants need to be ordered before surgery.

8. Most of them are supplied in pre-sterile packs and those supplied otherwise are autoclaved in the hospital CSSD.

9. The identification and traceability of each implants used is maintained by pasting the respective bar coded identification stickers in the OT / Cath Lab register and respective patient case sheets.

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| Chief Medical Administrator | | Chairman & Managing Director | |


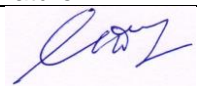
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| Document Title : Policies on Implantable prosthesis and medical devices | | | |


It is important to write both the serial number and stick the bar code stickers in the register and case sheet so that the serial numbers are available even if the barcode stickers become illegible in future.

10. The respective clinical departments are responsible for counseling for the usage of implantable prosthesis and medical devices. This includes the benefits and precautions and precautions to be taken while living with devices like pacemakers. They are also counselled on do and don'ts related with the implant / device including contraindicated medications where applicable. They are also counselled on situations where immediate hospitalization may be required.
11. The clinical departments, DTC, Biomedical Engineering and Purchase department monitors communications from regulatory authorities, manufacturers and patient feedback on devices. Recalls are implemented when recommended by manufacturer or regulatory authorities
12. A device recall is always done under the supervision of Chief Medical Administrator by a team consisting of him / her, Biomedical Engineer, Material Management In-charge and representative from medical specialty where applicable.
13. All patients who are affected are informed and recall / replacement arranged based on parameters of such recall program.
14. Legal opinions are sought when hospital patients are involved in such recall incidents and hospitals legal liabilities are reviewed before recall is instituted and patients informed.
15. The hospital shall document and maintain details all such recalls.
16. Unused implants and devices from hospital stock of falling under the recall parameters are identified and quarantined in central stores under lock and key till clarity of their handling is received from manufacturer and or regulatory authority

STANDARDS REFERENCE

MOM 10 – a,b,c,d,e

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| Document Title : Central Pharmacy | | | |

| | |
|---------------------|--|
| SUMMARY | This document provides instruction and guidance to the functioning of the Central Pharmacy of the hospital responsible for purchase and distribution of medications to retail pharmacies and other areas of the hospital |
| DISTRIBUTION | To all departments, units and wards through the Hospital Manual |

1. PURPOSE:

To define and describe the system of receipt, inspection, storage and issue of drugs at the central pharmacy.

2. SCOPE:



This procedure is applicable for all drugs and therapeutics purchased / supplied to the hospital.


3. DEFINITIONS

Drugs – For the purpose of this procedure and manual, drugs include prescription medications, samples, over-the-counter drugs, vaccines, sera, diagnostic and contrast agents administered to in-patients / out-patients to diagnose, treat or prevent diseases / conditions. These shall be inclusive of radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives, intravenous solutions etc.

4. RESPONSIBILITY

The Pharmaco-Therapy Committee is responsible for the approving various types drugs and manufacturers to be procured for use in the hospital.

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The Chief Pharmacist is responsible for overall management of the central pharmacy.

The Pharmacist – In-Charge Central Pharmacy is responsible for receipt, inspection, storage and issue of various drugs and therapeutics at the central pharmacy.

5. DESCRIPTION

The central pharmacy acts as point of procurement, receipt and storage of drugs to the hospital. It issues drugs to the retail pharmacies, surgical store, relevant sub-stores and units based on requisitions.

5.1 Purchase Functions

All purchasing of drugs and therapeutics shall be in accordance with the procedures for *Drugs and Therapeutic Committee*.

Central Pharmacy shall only purchase approved medications as per updated formulary of the hospital.

Vendors / Pharmaceutical Distributors for various approved medications are selected and rate contracts entered to them where possible. Efforts are made to make rate contracts / supplies from the approved company where possible. The list of vendors area maintained in the Hospital Management Information System (Mednet).



The reorder levels for all medications are set in the central pharmacy module of the Mednet software and purchase done at reaching the reorder level. Reorder levels are monitored based on seasonal variations in prescription for drugs and also based on various rate / discount offers from approved suppliers.


On reaching re-order level the Pharmacist assigned to manage purchase process inform the concerned supplier on phone the requirement on conformation of availability and time for delivery issues the purchase order generated from Mednet. The Purchase Order is mailed to the supplier.

Stock outs at vendor level and delays in supply are monitored for vendor evaluation and change of vendors where possible.

5.2 Receipt & Inspection of Items

All drugs and therapeutics supplied to the hospital shall be received by the central pharmacy after necessary security checks / clearance.

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The Pharmacist shall inspect the materials (Refer to *Checklist for Inspection of Drugs & Therapeutics*).

The pharmacist shall enter the particulars of the Invoice in the computer and generate a Goods Receipts Note (GRN) and obtain printed copies of the same (1+2 Copies).

The Chief Pharmacist shall verify the GRN, attach it with Invoice, sign and send the whole set to the Chief Administrator. Upon approval by the Chief Administrator the original GRN and Invoice copies shall be forwarded to accounts department for payment. A dispatch Register shall be maintained for the same.

All material received by the Central Pharmacy shall be recorded in the Central Pharmacy Stock Register.

5.3 Rejected / Non-Conforming Items

All rejected / non-conforming items shall be identified and stored separately. All such items shall be sent back to the suppliers, as soon as possible.

5.4 Storage of Items

The items are stored company wise and in alphabetic order.

All shelves and racks shall be appropriately labeled and identified.



All items, which are of expensive nature, shall be maintained separately under lock and key.


The items shall be stored as per the storage instructions with regard to the temperature and light exposure. All items requiring refrigeration shall be maintained in the centralized refrigeration unit. The temperature conditions inside the refrigerated storage shall be monitored on a daily basis.

5.5 Controlled Drugs / Narcotics

The various drugs and therapeutics controlled by provisions of the Drugs and Cosmetics Act shall follow the norms laid down for the same.

The suppliers for these items shall be as specified by the relevant government agency.

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5.5 Issues

The Central Pharmacy issues drugs & therapeutics to the retail pharmacy, Surgical Stores and sub-stores like Cath Lab Sub-store, Radiology Sub-Stores etc.

The issues to these stores shall follow the procedure specified for each of these areas. (Refer to the respective procedures).

5.6 Medications not listed in Pharmacy

a. Prescribing / Ordering of a Medication Not Listed in Formulary

The online ordering system for medications does not allow for ordering of medications not listed in the formulary.

Only consultants are allowed to prescribe / order a medication not listed in formulary. In such cases the ward nurses obtain the medication order / prescription on the hospital prescription pad with signature and credentials of the prescribing consultant and the same is sent to Central Pharmacy

b. Review and Approval of Request of Medication Not Listed in Formulary

The pharmacists from the central pharmacy will honor the prescription after approval of same by Chief Pharmacist who will countersign the medication requisition / prescription and procure the same as a local purchase. Any such local purchase of value more than Rs. 5000/- will be put up for the approval by Chief Medical Administrator who will countersign the medication order on approval.



c. Issue


The central pharmacy on procurement shall supply the medication directly to the ward.

d. Documentation and Evaluation of Local Purchases on Non-Formulary Medications

The details of procurement of medications not listed in formulary are noted in a separate register. The collated information of the same is reported to the Pharmacy & Therapeutics Committee monthly.

e. Future ratification and addition to Formulary

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In case of repeated requirement of the same medications the Central Pharmacy and PTC will coordinate with the consultant to initiate a procedure for adding the medication to the hospital formulary.

The above procedure is applicable only for procurement of a unavailable medication or strength variations and forms of medications listed in formulary and not to obtain a brand of medication not approved by formulary


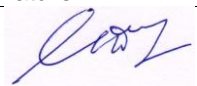
5.7 Statutory Records


All records as specified by the licensing and inspection authority (Office of the Drugs Controller) shall be maintained.

6. RECORDS



| Record Code | Record | Format | Responsibility | Indexing | File No | Minimum Retention Period |
|-------------|---------------------------------|------------|----------------|----------|---------|--------------------------|
| R-MAT-22 | Central Pharmacy Stock Register | Electronic | Pharmacist | Nil | Nil | Till Obsolete |

7. Amendment History

| Sl. | Current Revision | Nature of Change | |
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| Recommended By | Signature | Approved By | Signature |
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| | Edition No | Revision No. | Date | |
|---|------------|--------------|-------------|---|
| 1 | 01 | 00 | 1 July 2021 | Updated medication procurement process and process to procure medications not listed in formulary |
| 2 | 01 | 01 | 20 Oct 2021 | Further clarification on procedure to procure medications not listed in formulary |
| 3 | 01 | 02 | 1Nov 21 | General editing and renumbering |

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PHARMACY & MEDICATION MANAGEMENT MANUAL

Document Title : Retail Pharmacy

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| Doc No | SDH/MOM/4.15 |
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| | |
|---------------------|---|
| SUMMARY | This document provides instruction and guidance to the functioning of the Retail Pharmacies of the hospital located at various floors of the hospital |
| DISTRIBUTION | To all departments, units and wards through the Hospital Manual |

1. PURPOSE:

To define and describe the system of sales and issue of drugs and therapeutics through the retail pharmacy.

2. SCOPE:

This procedure is applicable for all issues and sales through the retail pharmacy covering outpatients, inpatients and to general public.

3. DEFINITIONS

Drugs – For the purpose of this procedure and manual, drugs include prescription medications, samples, over-the-counter drugs, vaccines, sera, diagnostic and contrast agents administered to in-patients / out-patients to diagnose, treat or prevent diseases / conditions. These shall be inclusive of radioactive medications, respiratory therapy treatments, parenteral nutrition, blood derivatives, intravenous solutions etc.

4. RESPONSIBILITY

The Chief Pharmacist is responsible for overall management of the retail pharmacy.

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The duty pharmacists are responsible for managing sales and issues to out patients and processing requisitions from the inpatient areas and units.

5. DESCRIPTION

The retail pharmacy is the point of sales and issue of drugs and therapeutics to outpatients, public and inpatient areas. It also acts as a point of supply of drugs and therapeutics to the various units of the hospital for replenishing their ward stocks / emergency stocks.

5.1 Requirements as per License

The pharmacy shall adhere to rules and regulations laid down by the relevant acts / rules governing its function and notifications issued from time to time by the office of the Controller of Drugs and Pharmaceuticals, Government of Maharashtra.

All statutory records that are required by the licensing authority shall be duly maintained.



5.2 Requisitions to Central Pharmacy

The Pharmacist shall make the Pharmacy Requisition whenever the Stocks at the Retail Outlet go below the re-order levels.

The Pharmacist shall verify the supply from the Central Pharmacy on receipt of the items and take them into retail pharmacy stock.

5.3 Issues to outpatients and outside customers

The drugs and therapeutics shall be issued against prescriptions only. The pharmacists shall verify the prescriptions carefully.

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In case of the particular brand of drug being prescribed is not available, a substitute generic shall be issued after consultation with the prescribing physician or surgeon, and this is documented on the prescriptions.

All issues to outpatients and outside customers shall be made against payment only.

All sales / issues shall have a Cash Bill a copy of which shall be provided to the customer / outpatient. All such bills shall contain relevant details like patient identification number, patient name and prescribing physician / surgeon.

The issuing pharmacist shall verify the issued items against the cash bill. They shall also advise the patient on the dosage and frequency of medication as prescribed, contraindications, life style adjustments needed in view of effects of the particular medication etc.

5.4 Issues to In-patients



The issues to In-patients shall be made directly to the concerned nursing unit and directly billed online to the patient account on a credit/debit basis.

The concerned nursing staff shall send an In-patient Pharmacy Requisition based on the prescription / instruction of the concerned physician / surgeon. These requisitions shall ideally cover the required medications needed for a patient for a maximum of 24 hours.

5.4 Issues to Units

The user departments shall raise a Material Requisition –cum-Issue Slip detailing the required drugs and therapeutics to replace used / expired items in their ward stock / emergency carts.

All units shall maintain a Minimum Stock Level and re-order levels for all their ward stocks and emergency carts.

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The retail pharmacy shall issue the required drugs and therapeutics as per the Material Requisition – cum – issue slip. The retail pharmacy shall maintain a record of overall stocks maintained issued to each unit.

All such issue of drugs and therapeutics, billed at Inpatient / Emergency shall be collated into the overall sales of retail pharmacy through the HIS.

6. RECORDS

| Record Code | Record | Format | Responsibility | Indexing | File No | Minimum Retention Period |
|-------------|---------------------------------|------------|--------------------|---------------|---------|--------------------------|
| R-MAT-23 | Pharmacy Requisition | Electronic | Pharmacist | Nil | NA | |
| R-MAT-24 | In-patient Pharmacy Requisition | Electronic | Nursing in-charges | Chronological | NA | 1 Year |

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| | | Issue No | 01 |
| | | Rev No. | 01 |
| | | Date | 1 Nov 21 |
| | | Pages | 1 |
| Document Title : Quality Assurance in Pharmacy Services | | | |

| | |
|---------------------|---|
| SUMMARY | This document provides instruction and guidance ensuring quality assurance of pharmacy services through audits and other mechanisms |
| DISTRIBUTION | To all departments, units and wards through the Hospital Manual |

1. PURPOSE:

To describe the processes established for quality assurance in pharmacy services of the hospital.

2. SCOPE:

This procedure is applicable to managing of quality of medication management practices within the hospital including selection and procurement drugs and therapeutics, storage and preservation, dispensing, administration and monitoring of medication effectiveness.


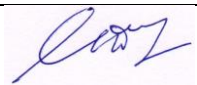
3. DEFINITIONS

Nil

4. RESPONSIBILITY

The Drugs and Therapeutics Committee is responsible for overall monitoring and implementation of the quality assurance system established for pharmacy services and medication management within Saideep Hospital.

The Chief pharmacist will have the responsibility for ensuring adherence to various practices as described in this procedure and coordinating the quality assurance practices through out all storage, dispensing and issue points for drugs through out the hospital.

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5. DESCRIPTION

Pharmacy services and medication management forms a vital component of the overall hospital services contributing to palliative, symptomatic and curative treatments of diseases and conditions.

A quality assurance program for the pharmacy services covering the safe and effective medication management practices within the hospital involves various individuals and units working in close coordination.

The quality assurance program shall cover the following aspects of the pharmacy services and medication management system.


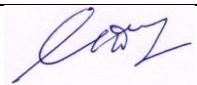
- Selection and procurement of drugs
- Storage and Preservation of Drugs
- Dispensing Practices
- Drug Information Services
- Administration of Drugs and monitoring of effects at units
- Control of high risk / controlled drugs
- Customer Feedback


5.1 Selection and procurement of drugs

The drugs available for dispensing and administration within the hospital shall be selected, listed and procured as per the hospital formulary.

The hospital formulary shall be compiled under the active guidance and participation of the Drugs and Therapeutic Committee.

The drugs included in the formulary shall be selected based on sound therapeutics, good benefit-to-risk ratio and cost effectiveness.

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The formulary should aim at

- a. Promotion of rational therapeutics
- b. Prevention of unnecessary duplication, waste and confusion
- c. Delivering cost optimization to both patients and the hospital

The additions and deletions of drugs to the formulary shall be the responsibility of DTC (Refer to the relevant procedure for more details).

The formulary shall include indications for use, effectiveness, risks and costs.

5.2 Control of Expired Medications / Non-Conforming Items

Control of Expired Pharmaceuticals & Therapeutics at Central Pharmacy, Retail Pharmacy and Surgical Store

The respective pharmacy / stores in-charges will generate a two lists from the HIS.


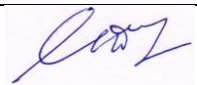
- Items nearing expiry (3 months from expiry date)
- Items for expiry (1 month from expiry date)


The items with short expiry times (less than six months); if any shall be identified under the second category if their expiry dates falls within a period of four weeks.

A physical verification shall be performed to identify and tally these items.

All items for expiry shall be removed from the stock and segregated to a separately identified rack / shelf. These shall be returned to the manufacturer/ supplier and credit notes obtained for the same.

The items nearing expiry shall be monitored on a daily basis and shall be issued on a priority basis. Efforts shall be made in coordination with the user department for their first use.

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Control of Expired Pharmaceuticals & Therapeutics at Units

The responsibility for identification, segregation and return of expired drugs in stocks / emergency supplies at the various units lies with the respective unit in-charges.

At the beginning of every month the unit in-charge or a person assigned by the unit in-charge shall physically verify the stocks, emergency trays, refrigerators etc. for expired drugs (All drugs falling within the period on one month within the date of expiry and four weeks for short expiry drugs; shall be considered expired).

On identification of expired drugs they shall be segregated, listed and forwarded to the pharmacy for replacement.

Random Checks / Inspections

The Chief pharmacist will perform random checks at various units / stocks for effective implementation of the control of expiry drugs. In case of discrepancies he shall make arrangements for immediate segregation and replacement of those items and shall report the matter to the next meeting of the PTC.


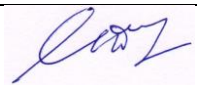
DTC also may consider surprise hospital wide inspection to verify the implementation of the system by the various units.


Non-conforming Items

The common type of non-conformance in case of pharmaceuticals and therapeutics are damages, opened containers, exposure to unfavorable storage conditions etc.

The periodic physical inspections of the stocks shall be done to identify these non-conformances and these items segregated and suitably disposed.

All units shall consider those items stored in room temperature for long periods (Incase of drugs to be maintained under refrigeration) as non-conforming. Efforts should be taken to avoid such exposures.

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Highly sensitive items like vaccines should be periodically examined to ensure their integrity.

5.3 Drug Information Services

The chief pharmacist in coordination with the DTC shall run an active drug information service within the hospital with a view of keeping medical, nursing and pharmacy staff up-to-date with continuous change and development on matters relating to drugs.

The information service shall issue regular bulletins on new drugs, banned drugs, adverse drug reactions etc. These bulletins shall be circulated to all units and clinical staff. These shall be prominently displayed in appropriate notice / display boards. The chief pharmacist shall maintain a central repository of such information and bulletins.

5.4 Customer Feedback


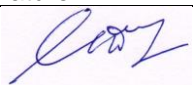
The chief pharmacist shall be responsible for obtaining feedback from patients, relatives, staff and outside customers regarding the services of the pharmacy including staff courtesy, promptness of service, adequacy of patient education, effectiveness of drug information services etc.

The patients shall be provided an avenue for providing feedback and registering complaints through feedback forms, complaints / suggestion books or complaints / suggestion boxes provided at convenient location.

An analysis of such feedback shall be done and report submitted to the hospital management.

5.5 Quality / Performance Indicators


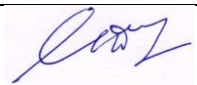
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| Chief Medical Administrator | | Chairman & Managing Director | |

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|  SAIDEEP HEALTHCARE & RESEARCH PVT. LTD. | SAIDEEP HOSPITAL PHARMACY & MEDICATION MANAGEMENT MANUAL | Doc No | SDH/MOM/4.16 |
| | | Issue No | 01 |
| | | Rev No. | 01 |
| | | Date | 1 Nov 21 |
| | | Pages | 6 |
| Document Title : Quality Assurance in Pharmacy Services | | | |

6. RECORDS

| Record Code | Record | Format | Responsibility | Indexing | File No | Minimum Retention Period |
|-------------|-------------------------------|-------------------|------------------|----------|---------|--------------------------|
| R-MAT-24 | Adverse Drug Reaction Reports | Electronic/Manual | Unit charges In- | Nil | NA | 3 Years |
| R-MAT-25 | Medication Error Reports | Electronic/Manual | Unit charges In- | Nil | NA | 3 Years |

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|  SAIDEEP HEALTHCARE & RESEARCH PVT. LTD. | SAIDEEP HOSPITAL PHARMACY & MEDICATION MANAGEMENT MANUAL | Doc No | SDH/MOM/4.17 |
| | | Issue No | 01 |
| | | Rev No. | 00 |
| | | Date | 21 Oct 2021 |
| | | Pages | 1 |
| Document Title : Procedure for Medication Recall | | | |

| | |
|---------------------|---|
| SUMMARY | This document provides instruction and guidance for recall of non-confirming medications from all locations of the hospital |
| DISTRIBUTION | To all departments, units and wards through the Hospital Manual |

1. PURPOSE:

To establish an effective process for medication recall in the hospital.

2. SCOPE:

This procedure is applicable to all situations of medication recalls including drugs issued to patients.

3. DEFINITIONS

Nil



4. RESPONSIBILITY


The Chief Pharmacist is responsible for leading and coordinating an effective drug recall effort across the hospital.

The Chief Medical Administrator along with the Chair of Drugs and Therapeutics Committee is responsible for ordering a medication recall

The Drugs and Therapeutics Committee is responsible for overall evaluation of the drug recall process and suggest on improvements to process.

5. DESCRIPTION

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| Chief Medical Administrator | | Chairman & Managing Director | |

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| Document Title : Procedure for Medication Recall | | | | |

5.1 Approval and Planning for a Medication Recall

The decision for recall shall be based on following scenarios.

- Based on communication from state and central drug authorities
- Information received from manufacturers / suppliers
- Based on internal review of medication related incidents like damage, impurities, possible breakage of cold chain conditions etc
- Based on internal review of adverse drug events related to same medication or particular batches of a medication

The requirement for a medication recall based on above scenarios is discussed by Chairperson of DTC, Medical Superintendent and Chief Pharmacist. On decision the official circular approving the medication recall is issued by Medical Superintendent and shall contain the details like generic name, trade / brand name, manufacturer name, batch detail, expiry dates etc are relevant.

The Chief Pharmacist along with the central pharmacy would plan for the medication recall by preparing a list of issue of the medication / selected batches and their issues to retail pharmacies, wards / units stocks, emergency drug carts / crash carts and patients based on data from the systems.



5.2 Procedure for Identification, Collection and Return Recalled Medications


a. Identification and Removal from Units / Wards / Emergency Medication Trolleys

- The same is coordinated with all units by various pharmacists with the aid of the issue lists and the recalled medication units.
- Medication units collected from each area / unit are stored separately in paper bag / carton and labelled with the unit / area name from which it was collected

b. Identification and Removal from Retail Pharmacy Stocks

- The same is lead by the respective retail unit pharmacists.

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| Document Title : Procedure for Medication Recall | | | |



- The medications removed from stock will be tallied and labelled and returned to pharmacy. Same is updated in the HMIS as stock returns.
- c. Recall of medication issued to patients
 - For the IP patients, the remaining units are tracked using the issue list and same collected from the patients. Alternate medication (substitute brands or unaffected batch) shall be provided as replacement to avoid any disruption in medical care.
 - Medications collected from each patient is stored in separate paper bag / pouch and labelled with patient name and UHID.
 - For discharged patients and OP patients the pharmacists shall list them out and make an effort to reach out to them on telephones based on contact number available in HMIS. A warning SMS would be send to all such patients warning them about the recall. The patients shall be advised to return and replace the recalled batches at the hospital pharmacy or dispose the recalled medications
- d. Tallying of the recalled medications shall be done by the Central Pharmacy team and a report on same shall be provided quantifying the quantity of recall medication originally procured and issued, numbers recalled and collected, no of patients possibly affected etc.


5.3 Review, analysis and Further Actions on Medication Recall

The recalled medications may be returned to supplied or disposed of as biomedical waste (after ensuring that they can't be scavenged for reuse).

Efforts shall be undertaken by the DTC and hospital quality team to identify and document any possible ADE related to the medications involved in the recall by retrospective review process combining medical records review and survey of the patients involved.

The DTC shall discuss in detail during monthly meetings any recalls that happened during the period evaluation circumstances leading to the medication recall and the effectiveness of the recall process based on report of same provided by the Central Pharmacy team.



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| Document Title : Procedure for Medication Recall | | | | |

The DTC shall inform the regulatory authorities about the recall and / or the possible ADEs that resulted in the recall based on circumstances of the each of the medication recall.

6. RECORDS

- Medication Recall Circulars
- Medication Recall Process Reports
- Minutes of Meeting of DTC

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|  SAIDEEP HEALTHCARE & RESEARCH PVT. LTD. | SAIDEEP HOSPITAL PHARMACY & MEDICATION MANAGEMENT MANUAL | | Doc No | SDH/MOM/4.18 |
| | | | Issue No | 01 |
| | | | Rev No. | 00 |
| | | | Date | 21 Nov 21 |
| | | | Pages | 1 |
| Document Title: Measure to prevent catheter and tubing misconnection during medication administrations | | | | |

| | |
|---------------------|--|
| SUMMARY | This document provides instruction and guidance for to establish measures to avoid catheter and tubing misconnections during administration of medications |
| DISTRIBUTION | To all departments, units and wards through the Pharmacy and Medication Management Manual |

1. PURPOSE:

To prevent catheter and tubing mis-connections during medication administration.

2. SCOPE:

This procedure is applicable to medication administrations at all locations and settings with in the hospital.

3. DEFINITIONS

Nil


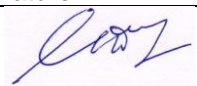
4. RESPONSIBILITY


The Nursing Superintendent is overall responsible for ensuring compliance to this procedure.

The nurses involved in medication administration is responsible for ensuring the prevention measured are implemented.

5. DESCRIPTION

1. Saideep has systems and procedures in place which:


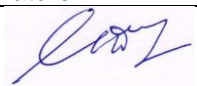
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| Document Title: Measure to prevent catheter and tubing misconnection during medication administrations | | | |

- a) Emphasize to non-clinical staff, patients, and families that devices should never be connected or disconnected by them. Help should always be requested from clinical staff.
 - b) Require the labelling of high-risk catheters (e.g. arterial, epidural, intrathecal). Use of catheters with injection ports for these applications is to be avoided.
 - c) Require that caregivers trace all lines from their origin to the connection port to verify attachments before making any connections or reconnections, or administering medications, solutions, or other products.
 - d) Include a standardized line reconciliation process as part of handover communications. This should involve rechecking tubing connections and tracing all patient tubes and catheters to their sources upon the patient's arrival in a new setting or service and at staff shift changes.
 - e) Bar the use of standard Luer-connection syringes to administer oral medications or enteric feedings and preferring Using only oral/enteral syringes to administer oral/enteral medications and avoiding the use of adapters and three-way taps.
2. Saideep gives training on the hazards of misconnecting tubing and devices into the orientation and continuing professional development of practitioners and healthcare workers.
 3. Saideep prefers purchasing of tubes and catheters that are designed to enhance safety and to prevent misconnections with other devices or tubes.

6. RECORDS

Nil

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| | | Issue No | 01 |
| | | Rev No. | 01 |
| | | Date | 1 NOV 2020 |
| | | Pages | 1 |
| Pharmacy Return Policy | | | |



Saideep Medical Store pharmacy has the following policy for return of medicines/ other products sold to the clients on OPD as well as IPD basis.


i. Items are eligible for a return exclusively under the following circumstances.

- Product(s) dispensed do not match the prescription.
- Product(s) were delivered in damaged/non-working condition.
- Product(s) have missing parts or accessories or different from their description on the product page.
- Product(s) are returned in original packaging i.e. with labels, barcode, price tags, original serial no. etc.
- Batch number of the product(s) being returned matches with the one(s) mentioned in the invoice.
- Product(s)/medicines(s)/bottle(s) are unused.
- Opened medicine strip(s)/bottle(s) are not eligible for returns.
- The damages/defects are covered under the manufacturer's warranty only.
- Medicines once dispensed are eligible for return within the 6 months from the date of invoice in case the drugs are stopped on doctor's order e.g. allergic reaction, ADR, change in the line of treatment etc.
- (Above all the drug name, strength, batch number and expiry date must be visible.)

ii. Certain categories of products are not eligible for return

| Categories | Type of products |
|----------------------------------|---|
| Temperature controlled medicines | Vials, Injections, Pen-fills, Vaccines or other products or specialty medicines cold storage |
| Baby Care | Breast Pumps, Diapers, Ear Syringes, Wipe Warmers, Bottle Nipples |
| Food and Nutrition | Health supplements and drink |
| Healthcare device | Glucometer Lancet, Healthcare Devices, Surgical, Health Monitors |
| Sexual Wellness | Condoms, Fertility Kit, Lubricants, Pregnancy Kit |
| Personal Care | Oral Care (Toothbrushes, toothpastes, mouthwashes etc); Feminine Hygiene (Sanitary Pads, Panty Liners, Menstrual Cups etc.); Shaving and Hair Removal (Men's Shaving – Razors, Blades, Shaving Foams, Brushes etc.; Men's Beard Care – Beard Oil, Beard Serum etc.; Women's Hair Removal – Wax Strips, Creams, Razors etc |
| Family Nutrition | Infant Baby Food, Toddlers' and Kids' Health Drink |
| Vitamin and Mineral Supplements | Core Letter Vitamins, Multi-Vitamin Preparations |
| Health Care Product | Ayurveda Products, Pain Relief Products, Herbal Supplements, Medical Supplies, Adult Diapers, COVID masks (N95, surgical masks and others if unpacked) |
| Others | Any wearable (COPD vest, bandages, bandage, knee caps) and any item (solid, gel, aerosol) which may have been partially used |



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| | | Pages | 2 |
| Pharmacy Return Policy | | | |

iii. Return Process:

1. To return the eligible items the customers are directed to the exclusive return counter.
2. The customer is required to handover the product in original packaging.
3. Refund will be initiated once Saideep Medical Store receives the product and verifies the same.
4. Refunds are carried out immediately either in cash or by bank transfer depending upon the amount of refund.
5. Refunds cannot be processed to third-party accounts. The name on Saideep Medical Store account should match with the name of the bank account holder. Saideep Medical Store will not be liable for any delay caused in refunds due to delay by third party affiliates (including banks), in providing information by the customer, technical issues and other reasons beyond its control.



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|  <p>SAIDEEP HEALTHCARE & RESEARCH PVT. LTD.</p> | <p>SAIDEEP HOSPITAL</p> <p>MATERIALS MANAGEMENT</p> <p>MANUAL</p> | Doc No | SDH/MMD/5.2 |
| | | Issue No | 01 |
| | | Rev No. | 01 |
| | | Date of Issue | 1 Nov 21 |
| | | Pages | 1 |
| Document Title : Purchase System | | | |

1. PURPOSE:

To define and describe the system of purchase of all materials including drugs required for functioning of the hospital.

2. SCOPE:

This procedure is applicable for the purchase of all category of items / materials including consumables and medicines.

This procedure is exclusive of purchase of equipment by the hospital both for Medical and Non-Medical purposes.


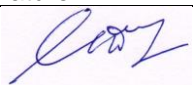
3. DEFINITIONS


Nil

4. RESPONSIBILITY

The MMC is responsible for the issue, approval and monitoring of tenders / contracts.

The DTC is responsible for the selection of drugs & therapeutics, approving manufacturers and suppliers, issuing and approval of tenders pertaining to drugs and therapeutics procured by the hospital.

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| Document Title : Purchase System | | | |

The Director –Dr K R Jhalani is responsible for approval of all purchase orders of value up to Rs. 5,00,000.

The Hospital Administrator is responsible for approval of all purchase orders of value up to Rs. 1,00,000.

The Coordinator Materials Management is responsible for approval of all purchase orders including drugs and therapeutics.

The Coordinator Materials Management is responsible for planning and execution of purchase activities and ensuring that all appropriate records for the same are maintained.


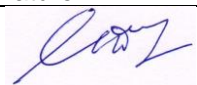
The Coordinator Materials Management is responsible for preparation and verifications of purchase orders prior to their submission for approval.


The Chief Pharmacist is responsible for preparation and verification of the purchase orders pertaining to drugs and therapeutics.

The concerned department / units heads and stores in-charges are responsible for coordinating with the purchase personnel in effective planning of the purchase process and forecasting the material consumption patterns.

5. DESCRIPTION

5.1 Vendor Registration and Selection

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| Document Title : Purchase System | | | |

The Coordinator Materials Management with the assistance of the Purchase Assistant shall maintain a database of registered suppliers. This database shall be organized as per the various Inventory heads.

The Chief pharmacist shall be responsible for maintaining the same for the drugs and therapeutics.

The hospital shall strive to maintain at least three registered suppliers for each items used by the hospital.

The registration of each supplier shall be based on *Criteria for Approval of Suppliers*.

The final selections and approval of suppliers; and awarding of tenders / contracts shall be done in consultation with the MMC or PTC and concerned functional heads in the respective areas.


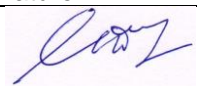
5.2 Tender / Quotation Process


Tenders / Quotations should be obtained for all items / equipments costing more than Rs. 50,000/-. Tenders can be called for through advertisements or directly from registered firms.

There should be at least three bidders for a tender /quotation process to be valid. Incase of items / equipment of special nature where a single or few suppliers are available a single bidder may be requested for tender / quotation; after obtaining approval of the MMC/PTC.

For all tenders called for the lowest three bidders shall be short-listed. The Coordinator Materials Management shall prepare a comparative statement of the bidders short-listed for final negotiation.

The comparative statement shall cover the following details about the bids short-listed; Name & Details of Bidder, Make / Model, Price Per Unit, Quantity offered, Delivery Period, Terms of delivery, Past Performance of the supplier; etc.

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| Document Title : Purchase System | | | |

In case of tenders for equipment these comparative statements shall be accompanied by a technical and feasibility analysis reports prepared by a multi disciplinary team constituted by members from the concerned functional area, hospital administration, finance and bio-medical engineering.

5.3 Contracts

The purchase committee has the authority and responsibility to sanction rate contracts / running contracts to the tune of Rs. 10,00,000/- following the usual procedures for inviting quotations for supply / work etc.

Any rate contracts / running contracts above the value of Rs. 10,00,000/- has to be ratified by the CMD.


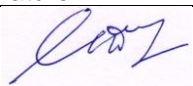
5.4 Short Quotations


Short quotations can be invited by the CMD for purchase of items / materials costing less than Rs. 50,000/- He should obtain the sanction of the CMD or Director –Dr K r Jhalani before effecting the purchase. All emergency purchases has to be ratified by the MMC in its next meeting. Maximum limits for emergency purchases are limited to Rs.50,000 / -.

5.5 Emergency Purchases

In cases of emergency, the Director – Dr K R Jhalani has the authority to waive the normal purchase system to place emergency purchases with in a maximum limit of Rs.50,000 /- . All emergency purchases have to be ratified by the MMC / PTC in the next meeting.

5.6 Purchase Orders

| Recommended By | Signature | Approved By | Signature |
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| Dr. Hrishikesh Kalgaonkar |  | Dr. S.S. Deepak |  |
| Chief Medical Administrator | | Chairman & Managing Director | |

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| Document Title : Purchase System | | | |

No goods / items, except cases of emergency purchases' shall be obtained without a written purchase order issued and signed by the competent authority.

The Hospital Administrator shall have the authority to sign and issue purchase orders for all purchases up to a value of Rs. 1,00,000/-.

The Director Dr K R Jhalani shall have the authority to sign and issue all purchase orders for purchases up to a value of Rs. 5,00,000 /-.


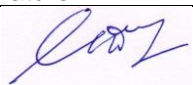
The CMD shall have the authority to sign and issue purchase orders for any purchases above the value of Rs.10,00,000/-


In case if any of the above approval authorities are not available for any period of time; their authority can be temporarily delegated to another staff member nominated by the CMD through an office order for a specified period.

The Purchase Assistant shall be responsible for preparation of the purchase orders and the Coordinator Materials Management for its verification before submission for approval and issue.

All purchase orders shall contain the following relevant information; Order Number, Date, Full Name and Address of the Supplier, Consignees' Name and Address, Terms & Conditions, Description of goods, Quantity, Supplier Quotation / Tender / Contract reference, Price terms, Payment Terms, Payment Mode, Delivery date and Schedule, Packing / Transport Instructions, Freight Payment terms, Insurance details, Inspection Details, Penalties, Special Terms and Conditions if any.

In case of amendments to the purchase orders, the same shall be incorporated and shall follow the same procedure before approval and issue.

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|  | SAIDEEP HOSPITAL MATERIALS MANAGEMENT MANUAL | Doc No | SDH/MMD/5.2 |
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| | | Pages | 6 |
| Document Title : Purchase System | | | |

5.7 Rating of Suppliers

The Coordinator Materials Management shall be responsible for the rating of the key suppliers at least once in a year.

The evaluation for rating shall be based on assessment of quality by both the Central Stores in-charge at the time of receipt and by the user department; separately for each items evaluated.

These ratings and details any violations of terms of the purchase order by any supplier shall be presented to the MMC / PTC on a periodic basis. The MMC / PTC shall take appropriate actions based on this feedback.

A Supplier Evaluation Sheets shall be used to record these feedback and these shall be maintained for all key supplier item wise.


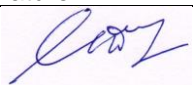
5.8 Purchase Records

The Coordinator Materials Management with the assistance of the Purchase Assistant shall ensure proper maintenance and updating of the following purchase related records.

- Purchase Indents
- Comparative statements
- Purchase orders
- Supplier Evaluation Sheets

6. RECORDS

| Record Code | Record | Format | Responsibility | Indexing | File No | Minimum Retention Period |
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SAIDEEP HOSPITAL
MATERIALS MANAGEMENT
MANUAL

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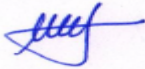

Document Title : Purchase System

| | | | | | | |
|----------|----------------------------|-------------------|----------------|---------------|-----------------|--------|
| R-MAT-01 | Purchase Indent | Manual | I/C Mat. Mgmt. | Chronological | MAT / F01 - PUR | 1 Year |
| R-MAT-02 | Purchase Orders | Electronic/ Print | Purchase Asst. | Chronological | MAT / F02 - PUR | 1 Year |
| R-MAT-03 | Supplier Evaluation Sheets | Manual | I/C Mat. Mgmt. | NA | MAT / F03- PUR | 1 Year |

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| JOB DESCRIPTION | |
| DESIGNATION: Pharmacy In-Charge of Purchase | REPORTING TO: Pharmacy In-charge, Director Pharmacy, Administrative Officer |
| DEPARTMENT: Pharmacy | RESPONSIBLE FOR Purchase of medicinal, Surgical and related products, wholesale as well as ad hoc basis. |
| QUALIFICATION: D-Pharm/ B-Pharm, , Past experience of purchasing in a major outlet & purchase unit for at least 5 years | TO BE REVIEWED: 1st April every year |
| SKILLS SET REQUIRED: Should have knowledge of purchase major pharmacy outlet, market analysis for seasonal trends, negotiating with sales reps and should be fluent in English, Hindi and Marathi. | |

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Role & Responsibilities


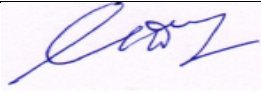
RESPONSIBILITIES AND ACCOUNTABILITIES:


- Wholesale purchase for the central pharmacy store.
- Managing ad-hoc purchase in case of stock out scenarios.
- Preparing purchase orders on monthly basis for bulk purchases based on the requisition received from the retail outlets.
- Supervision of received goods for quality as well as quantity.
- Supervision of GRN preparation and stock entry in the stock register.
- Coordinates with Pharmaco-therapeutics committee for major procurements.
- Communicates with operations head in the event of a drug shortage, drug recall scenarios.
- Preparing market analysis for the alternate brand availability to minimize purchase cost and communicating with Pharmacy Director.
- Takes feedback of inventory, goods movement and adjusting purchases accordingly.

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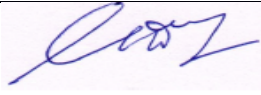
| JOB DESCRIPTION | |
|---|--|
| DESIGNATION: Pharmacy In-Charge of Operations | REPORTING TO: Pharmacy In-charge, Director Pharmacy, Administrative Officer |
| DEPARTMENT: Pharmacy | RESPONSIBLE FOR Daily functioning of all Pharmacy outlets, Sales, Inventory management. Staff management. |
| QUALIFICATION: D-Pharm/ B-Pharm, , Past experience of supervision a major outlet & purchase unit for at least 5 years | TO BE REVIEWED: 1st April every year |
| SKILLS SET REQUIRED: Should have knowledge of handling patients, billing and stock management, should be fluent in English, Hindi and Marathi. | |


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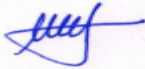

RESPONSIBILITIES AND ACCOUNTABILITIES:


- Looks after daily sales in all outlets.
- Manages inventory. Performs regular stock checks and generating stock report.
- Arranges and conducts periodic stock takings in Pharmacy.
- Prepares duty roster and ensures adequate manpower deployment in all pharmacy outlets.
- Heads monthly meetings for resolving problems and for the improvement of systems in the department.
- Generates various MIS Reports.
- Represents the Department in various meetings.
- Liaisoning between hospital administration and FDA authorities.
- Prepares the hospital formulary.
- Communicates with clinical staff about the changes in drug availability status by circulars, messages or notices.
- Communicates with government authorities for communicable diseases, schedule H drugs, narcotic drugs, Anti-TB drugs sales.
- Interacting with the patients / by standers to deal with any complaints or clarifications related to Pharmacy.

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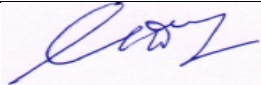
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| JOB DESCRIPTION | |
| DESIGNATION: Pharmacy In-Charge of Quality | REPORTING TO: Pharmacy In-charge, Director Pharmacy, Administrative Officer |
| DEPARTMENT: Pharmacy | RESPONSIBLE FOR: All statutory compliances, Quality monitoring especially NABH standards implementation. |
| QUALIFICATION: D-Pharm/ B-Pharm, , Past experience of 2 years in quality standards implementation | TO BE REVIEWED: 1st April every year |
| SKILLS SET REQUIRED: Should have knowledge of various healthcare and drug related laws, should be familiar with NABH standards, ISO standards etc. Should be fluent in English, Hindi and Marathi. | |

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RESPONSIBILITIES AND ACCOUNTABILITIES:

- Co-Ordinates with the Quality Department.
- Attends meetings and prepares reports connected to NABH.
- Monitors all pharmacy relevant patient safety, patient education standards are being implemented.
- Performs all relevant audits especially in NABH's COP, MOM chapters.
- Presents the MIS and audit reports to the superiors and contributes in quality improvement programmes.
- Prepares pharmacy quality improvement budget.
- Oversees the environmental surveillance and safe drug storage conditions. Looks after pest control in the storage areas.
- Promotes awareness in drug safety among patients/clients by preparing placards, bills, digital displays etc.
- Prepares and updates the high risk medicine list, LASA list.
- Monitors safe dispensing of medicines especially high risk drugs.
- Monitors on-the job training given to new recruits through Job rotation.
- Ensures proper implementation of the software related to Pharmacy and gives inputs and suggestions for improvement in the system.

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JOB DESCRIPTION

DESIGNATION: Pharmacy In-Charge

REPORTING TO: Director Pharmacy, Administrative Officer

DEPARTMENT: Pharmacy

RESPONSIBLE FOR General supervision of Pharmacy. Arranges and conducts periodic stock takings in Pharmacy. Heads regular meetings for resolving problems and for the improvement of systems in the department.

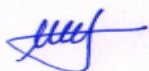

QUALIFICATION: D-Pharm/ B-Pharm, MBA desirable, Past experience of supervision a major outlet & purchase unit for at least 5 years

TO BE REVIEWED: 1st April every year

SKILLS SET REQUIRED: Should have knowledge of handling patients and should be fluent in English, Hindi and Marathi.

RESPONSIBILITIES AND ACCOUNTABILITIES:

- Supervision of all pharmacy outlets.
- Managing day to day working with pharmacy operational head, purchase head and quality head.
- Enhances professional growth and development through participating in educational programmes, attending meetings, workshops etc.
- Ensures proper implementation of the software related to Pharmacy and gives inputs and suggestions for improvement in the system.
- Participates in administrative staff meetings and attends other meetings as assigned.
- Performs other related duties as assigned or requested.
- Planning the yearly budget.
- Planning of manpower.
- Maintaining rapport with pharma businesses as well as the clinical heads within the institute for smooth functioning.


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| JOB DESCRIPTION | |
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| DESIGNATION: Pharmacist | REPORTING TO: Pharmacy In-charge, |
| DEPARTMENT: Pharmacy | RESPONSIBLE FOR Provides prescribed medications, drugs and other Pharmaceuticals as needed for adequate patient care according to Professional standards and practice. |
| QUALIFICATION: D-Pharm/ B-Pharm with FDA valid license. | TO BE REVIEWED: 1st April every year |
| SKILLS SET REQUIRED: Should have knowledge of handling patients' prescriptions and should be fluent in English, Hindi and Marathi, handling of pharmacy software. | |
| RESPONSIBILITIES AND ACCOUNTABILITIES: | |
| <ul style="list-style-type: none"> ➤ Dispense off medications as per the Physicians orders. ➤ Suggesting alternate brands, generic products in case of non availability of the prescribed brand after consulting the physician & pharmacy in charge. ➤ Preparing credit notes for the returned goods from the patients. Checking the returned goods packaging before accepting. ➤ Maintain prescription records. ➤ Prepare bill for medications as per the Physician's prescriptions from various OP and IP Departments through computer. ➤ Provide Patient medication counseling and education. ➤ Check stock on a regular basis to identify and reorder stock outage medications. ➤ Store drugs and pharmaceuticals as per the manufacturer guidelines. ➤ Assist in purchasing of drugs. ➤ Preparing GRN for received goods. ➤ Assisting in monitoring storage refrigerator temperature. ➤ Workplace cleanliness and tidiness. | |

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| | | Pages | 6 |
| Document Title : General Policies Pharmacy Services & Medication Management | | | |

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|---------------------|--|
| SUMMARY | <p>This document provides instruction and guidance to hospital staff on various issues related to pharmacy services and management of medication in the hospitals.</p> <p>The policy discusses the overall compliance to various standards pertaining to the Medication Management as per NABH standards; and links to further downstream policies and documentation established for compliance to standards specific to various issues like storage, ordering, administration, adverse reactions etc.</p> |
| DISTRIBUTION | To all departments, units and wards through the Pharmacy and Medication Usage Manual |

INTRODUCTION

This policy has been formulated to ensure as far as possible compliance to various standards pertaining to Management of Medications (MOM) as prescribed by the NABH Accreditation Standards.

PURPOSE AND SCOPE



The purpose of this policy is to guide the hospital staff in managing the process of medication management at various units of the hospital to ensure patient safety and wellbeing.


RESPONSIBILITIES

Chairman & Medical Director:

The overall responsibility of implementing the policy rests with the CMD of the hospital.

HODs / Unit Heads

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They are responsible for implementing the various guidance in terms of ordering and administration of medications.

Director In-charge– Pharmacy

Is responsible to ensure that the policies pertaining to pharmacy services are implemented.

POLICIES

A. Pharmacies

The hospital operates the following pharmacies;

Central Pharmacy: Upper Basement

OPD Pharmacy: Upper Basement & Ground Floor

IPD Pharmacies: On Floors 2,3,4,5,6 and 9th.

The Chief Pharmacist is responsible to ensure that these pharmacies to operate under updated and suitable licenses issued by the state drugs authority.

B. Drugs & Pharmacy Committee


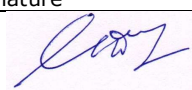
The hospital has a Drugs & Therapeutic Committee which is multi-disciplinary in nature and the committee is empowered to establish and monitor an effective medication management system in the hospital.


The constitution and working system of the committee is described in the relevant section of the hospital manual.

C. Drug Formulary

The hospital formulary shall be made available in all wards and department for easy reference. The same shall be accessible through the Hospital network.

The same is approved and periodically reviewed by the Drugs & Pharmacy Committee. All updating / amendments of the formulary have to be approved by the DPC.

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There are certain medications which are prepared in the hospital itself.

At times the hospital allows IP patients to procure medicines from outside, during situations like when the prescribed medicine is either out of stock or not included in the hospital's drug list or the patient wishes to purchase medicines from outside.

D. Purchasing and Procurement

The method of purchase of a drug in the pharmacy is by inviting tenders from the manufactures/wholesalers.

The Central Pharmacy will be the only purchasing and procurement point for medicines in the Hospital. The detailed procedure governing the purchase of medications is specified in the Pharmacy Services SOP.

The purchasing and procurement of drugs are controlled by the Drugs & Therapeutic Committee established by the hospital.

E. Policy for the Introduction of New Drugs


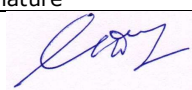
Introduction of a new drug in the hospital is based on the doctor's indent which, has to be approved by the drugs and therapeutic committee.


The procurement of a new drug is done by issuing purchase orders to the manufacturers/wholesalers.

All patients of Saideep Hospital & Research Pvt Ltd will be prescribed all the medicines they clinically require, based on their diagnosis from the hospital formulary.

To ensure the best use of resources there is a formal procedure for the introduction of new drugs. No new drug will be prescribed without prior authorization from the Drug and Pharmacy Committee.

For inclusion of the new drug in the formulary an application for the same would be sent to the Medical Superintendent. (Refer to the Bylaws of the Drugs & Pharmacy Committee)

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F. Obtaining of Drugs not listed in formulary

The method adopted to get an emergency drug that is not there in the formulary is done by:

- Identifying the different brands and manufacturers of the drug.
- Contacting the manufacturers/wholesalers/other hospitals.
- Placing an emergency purchase order.

On specific request the pharmacy will make arrangements for procurement of the same. This shall be done only in cases where the same is ordered through a prescription by the Head of Departments / Senior Consultants.

All such instances will be reported to the Chief Pharmacist on a weekly basis and subsequently DTC by the him / her on a monthly basis

G. Retail Pharmacy Operations.


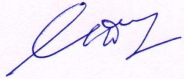
The method adopted by the retail pharmacy outlets in dispensing the drugs includes:


- Receiving the prescription on the basis of the queue.
- Billing the prescription.
- Issue of token on cash payment?
- Retrieving the medicine on the basis of the bill.
- Checking the medications retrieved on the basis of the prescription.
- Calling the token and issuing the drugs explaining to the patient regarding the drug intake, dos and don'ts etc.

H. General Policy on Expiry Checking

The medicines in the shelf of store, all retail areas, wards, critical care areas, OT etc. are checked once in every month for expiry date by the concerned staff responsible, the medicines are returned to the dealers 2 months prior to expiry date through the central (i.e. wholesale purchase) pharmacy.

There are 3 exceptions to this policy.

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1. All surgical items are sold till their last date of expiry / last day of the month of expiry for IPD cases only and that too for the same day use.
2. The cut strips of the medicines are returned to the dealers 1 month prior to expiry date through the central (i.e. wholesale purchase) pharmacy.
3. All medicines requiring a cold chain for storage are sold till their last date of expiry / last day of the month of expiry excluding any multi-dose vials / tablets which are available in bottles for the same day use.


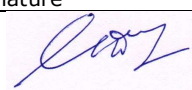
PROCEDURE (S)


The following policies have been established by the hospital to ensure an effective medication management system

- SDH/MOM/02 - Storage of Medications
- SDH/MOM/03 - Prescription of Medications
- SDH/MOM/06 - Medication Dispensing and Labeling
- SDH/MOM/08 - Medication Administration
- SDH/MOM/09 - Adverse Medication Events
- SDH/MOM/11 - Narcotics & Psychotropic Substances Handling
- SDH/MOM/05 - High risk medication
- SDH/MOM/12 - Chemotherapy Drugs
- SDH/MOM/13 - Radiotherapy drugs
- SDH/MOM/10 - Medication error
- SDH/MOM/04 - Verbal orders

Procedures have been established as a part of the Pharmacy Department Manual for defining and establishing a system for procurement, storage and dispensing of medications in the hospital;

- Procedure for Procurement of drugs
- Procedure for Central Pharmacy Operations

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- Procedure for Retail Pharmacy Operations

The hospital has established separate policy and procedure for reporting and analysis of Adverse Drug Events.

MONITORING

The Drugs & Pharmacy Committee monitors the adherence to the medication management policy and processes across the hospital.

Individual Nursing Unit in-charges are responsible for monitoring of the implementation of the policies and procedures pertaining to medication management at the ground level on a day-to-day basis.



REFERENCES

Standards

MOM 1 – a, b

MOM 2 – a, b, c, d, e, f

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