STANDARD OPERATING PROCEDURES (SOPs)

FOR PHARMACY (07)

EQUITY WITH QUALITY

Book 1

Department of Health & Family Welfare, GNCTD

SOP for Pharmacy

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Quality Assurance Cell
Delhi State Health Mission
Department of Health and Family Welfare
Government of NCT of Delhi

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CONTENTS

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Abbreviations

ADR	Adverse drug reactions
CPA	Central Procurement Agency
EDL	Essential Drug List
DDW	District Drugs Warehouse
DTC	Drugs and Therapeutics Committee
IPD	Inpatients Department
MCI	Medical Council of India
MDS	Main Drug Store
NABH	National Accreditation Board for Hospitals & Health care providers
NABL	National Accreditation Board for Testing and Calibration Laboratories
OPD	Outpatients Department
WHO	World Health Organization

Introduction

Provision of quality health care to the people is a commitment of Government of NCT of Delhi. Availability of quality medicines and their rational use is important for this to be achieved. Ensuring that essential medicines are available for the patients at all times and they are rationally used requires an awareness of the multiple steps involved in the "Medicine cycle", if the aim of ensuring that the right medicines is available for the right patient at all times has to be fulfilled. These steps include :-

1) Selection of a list of medicines which are essential to meet the health care requirements of the people . This is dependent on the morbidity and mortality pattern of that region. The word essential has been defined by the World Health Organization as

   "Essential medicines are those medicines that meet the priority health care needs of majority of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety and comparative cost effectiveness. Essential medicines are intended to be available at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and community can afford"

2) Assessment of the quantity of medicines that are required within the health facility. Accurate quantification is important to ensure that there are no shortages in availability of essential medicines for the patients.

3) Procurement of these medicines by the health facility. The process would be from the Central Procurement Agency of the Government(CPA) of the Delhi or the Delhi Health Corporation Ltd (DHCL) that has been made. In case medicines are not available in the CPA / DHCL these would have to be made available by the hospital for the patients by either borrowing from other hospitals or procuring locally.

4) Storage- The medicines obtained by the hospital must be stored in conditions to ensure that the quality of the medicine does not deteriorate. The storage must be as specified by the manufacturer.

5) **Distribution**-The medicines would have to be distributed to the different areas of use within the hospital- Main Drug store- Outpatient Pharmacy, Hospital Emergency, Inpatient departments. At each place, conditions for storage must be as specified in the manufacturers brochure.

6) **Prescribing** of medicines must be based on principles of rational prescribing

7) **Administration** of medicines must follow safe medication practices

8) **Dispensing** of medicines must follow good dispensing practices.

8) **Disposal** of medicines found unfit for use must be in accordance with the existing rules for bio- waste management

9) **Well Informed Patients**: Patients must be informed about proper use of medicines prescribed to them.

10) **Monitoring** of the Medicine Cycle within the health facility ie from the procurement to use.

11) **Education** of health care providers, including doctors, nurses and pharmacists on a continuous basis

12) **Correction/ Modification/ Changes in the processes** at any step based upon problems encountered

A thorough review of all these steps is required on a regular basis to ensure that quality medicines are available for the patients at all times and they are rationally used.

Such an elaborate process requires that there be Standard Operating Procedures (SOPs) for each step under defined conditions. They are necessary to ensure the proper conduct of processes, in continuity, to achieve quality performance. These must be available at all times in the locations where they are required.

These standard operating procedures have been made for management of medicines availability, distribution , storage and rational use within hospitals under Government of NCT of Delhi. They have been made keeping in mind the practices that are already in existence within the hospitals. It has been the endeavor of the Committee to make

the SOPs simple and easy to use. Experience of people involved in actually managing different aspects of medicine cycle has been used for making these SOPs. The Order of the SOPs is as they would be required in the different aspects of the Medicine procurement and use cycle within a hospital- Selecting medicines, quantification, procurement, storage, distribution, prescribing, dispensing, administration, monitoring, quality checks

In all this the role of the Hospital Drugs and Therapeutics Committee (DTC) will be paramount. It will play a key role in improving the use of medicines in the health facilities(hospitals). It is important that all hospitals establish DTCs as a first step to improving quality of management of drug use.

The first section deals with general aspects required in a health facility to ensure that essential medicines can be made available.

In the SOPs that follow the word "**drug**" has been used for **medicines**, as that is the word used in the Drugs and Cosmetics Act 1940. Although for therapeutics it is preferable to use the word "medicine".

For procurement of drugs CPA has been used interchangeably with District Drug Warehouses, as that is the way the Government proposes to distribute the medicines to the health facilities in the future.

Some SOPs have been adapted from those of the National Accreditation Board for Hospitals and Health Care Providers

These SOPs have been made as a preliminary guide for basic processes involved in the medicine procurement-use cycle. Once these are established and put in place, more SOPs to further strengthen the medicine (drug) cycle in the health facilities will be formulated.

Definition

"Drug" includes

(i) All medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) Such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of [vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) All substances intended for use as components of a drug including empty gelatin capsules; and

(iv) Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board

Drugs & Cosmetics Act, 1940

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Department:	PHARMACY	SOP	1
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Overall pharmacy services and usage of drugs in the health facility

1.1 Purpose

To provide guide lines for the organization of pharmacy services, management, procurement of drugs and their usage.

1.2 Scope

All activities and areas in a health facility (Hospital) concerned with procurement, storage, use and disposal of drugs.

1.3 Responsibility

- Head of the Institute
- DTC
- Departmental Heads
- Purchase Officer
- Officer in-charge MDS
- Pharmacist in-charge MDS
- Officer in-charge OPD Pharmacy
- Pharmacist in-charge OPD Pharmacy
- Nursing Sister in-charges of Department sub-stores.

1.4 Procedure

1.4.1 The overall management of pharmacy services in the hospital will be a coordinated activity involving the DTC, Purchase officer, Officer in-charge MDS, all Heads of departments, Pharmacist in-charge MDS and Pharmacy, Nursing Sister in-charge's of different wards and sub stores. They will all work under the guidance of the Head of the Institute.

1.4. 2 The Pharmacy shall comply with the following laws and regulations: Drugs and Cosmetics Act; Narcotics and Psychotropic Substances Act; Drugs and Magic Remedies Act.

1.4.3 The principles enunciated in the Drug Policy of Government of NCT of Delhi, 1994 (or any revision) shall be followed in the health facility

1.4.4 Only drugs as included in the Essential Drugs(medicines) List of Government of NCT of Delhi will be procured and used. In addition the health facility may specify other drugs which they specifically require for the patients. This will be decided by the DTC and justification for the same will have to be given. Inclusion of drugs must based on their efficacy, safety, suitability and cost.

1.4.5 Every hospital shall have a DTC which shall annually review the appropriateness of the health facility drug list to meet the needs of the health facility. The DTC will form the core group for coordinating all activities related to rational use of medicines in the health facility.

1.4.6 Scientific and rational principles will be followed for selecting the list of essential medicines for the health facility, estimating quantities of medicines required, storage, dispensing, prescribing, administering and use of medicines.

1.4.7 Documentation of all aspects related to the drug management cycle must be in place there and the records must be maintained preferably electronically. These must be audited regularly by Officers appointed by the Head of the Institute.

1.4.8 There should be a Hospital Information Management System(HIMS) for maintaining drug accounts, efficient procurement, distribution within the health facility and prescription details.

1.4.9 The health facility must specify the budget for drugs under a separate head ,"*Budget for Drugs".* The budget spent on drugs must never be clubbed together with other hospital consumables.

1.4.10 A system for providing updated information in relation to drugs, to the doctors, nurses, pharmacists, should be readily available within the health facility. Electronically available, peer reviewed sources of drug information can be used for the same.

1.4.11 The policies and processes of the health facility as regards the drug supply and their use cycle must be informed to all the health care providers within the health facility

1.4 12 A system for continuous monitoring of the drugs supply use cycle in the health facility must be established. The DTC must coordinate the monitoring within the health facility. Regular review, with an analysis of the strengths and weaknesses of the drug supply use cycle in the health facility must be done and corrective action should be taken for further improvement from time to time.

1.4.13 Standard Operating Procedures as specified for procurement, storage, distribution, dispensing, prescribing, administering, disposal of drugs must be strictly followed.

1.4.14 All processes must be followed, to ensure that patients receive appropriate drugs for their medical illness and do not suffer any harm.

1.5 Records

All records pertaining to activities related to drug supply use cycle as written in the specific SOP (SOP 2-18) must be maintained.

1.6 Process Efficiency Criteria

There should be no shortages of quality, essential drugs in the health facility for the patients. These must be stored and rationally used causing no harm to the patients.

1.7 Activity

All activities as related to drug supply use cycle as given in the specific SOP (SOP 2-18)

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Department:	PHARMACY	SOP	2
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for indenting of drugs from warehouse

2.1 Purpose

To establish procedures for indenting of drugs and items from DDW/ CPA for the hospital.

2.2 Scope

All activities related to determining the nature and quantity of drugs required by the hospital for indoor, outdoor and emergency patients and ensuring their availability at all times.

2.3 Responsibility

- Officer in- charge MDS
- Pharmacist in- charge MDS
- Ware house in- charge
- Officer in- charge CPA
- Pharmacist in-charge CPA

2.4 Procedure

2.4.1 The list of drugs to be indented must be in accordance with the EDL prepared by the Hospital DTC.

2.4.2 Officer In-charge MDS will determine the total quantity of the drugs required on an annual basis using the past consumption pattern, morbidity data & hospital requirements. A buffer stock of drugs for 90 days must be maintained by the hospital.

2.4.3 The total indent of drugs shall be approved by the Head of the Institute and foorwarded to the DDW . The indent will be sent to the DDW preferably electronically using Government approved software.

2.4.4 The indent should be sent quarterly i.e. four times a year to the DDW except in rare emergencies.

2.4.5 The DDW** will deliver the drugs to the hospital. It will be the responsibility of the DDW In-charge to ensure timely delivery of indented drugs to the MDS of the health facility.

2.4.6 These indented drugs will be received by the Pharmacist In-charge of the MDS of the hospital and counter checked by the Officer in-charge of the MDS of the hospital. A record of the same must be maintained preferably by Electronic means.

2.4.7 The Warehouse will only send those drugs to the health facility which have been declared "as of standard quality."

** Delivery of drugs by the DDW to the health facility is being proposed, hence the same has been incorporated.

2.5 Records

- List of essential drugs prepared by the DTC of the hospital.
- Total quantity of drugs estimated by the Officer In-charge of the MDS, based on consumption pattern, morbidity data and hospital demand, sent to the warehouse.
- The individual Indent vouchers sent to the warehouse.

2.6 Process Efficiency Criteria

- Timely indenting of drugs from warehouse
- Availability of all essential drugs in the hospital at all times.

2.7 Activities

- Review of timing of indents sent to the warehouse by Head of the Institute and Officer In-charge MDS.
- Review of availability of drugs in the hospital, by the DTC at quarterly intervals.

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Department:	PHARMACY	SOP	3
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for local purchase of drugs

3.1 Purpose

To ensure availability of essential drugs in the hospital that were not obtained through regular indenting from the DDW and to meet special requirements, medical emergency situations and exigencies of the hospital.

3.2 Scope

Emergency and Indoor Patients. It should preferably not be used for OPD patients.

3.3 Responsibility

- Hospital DTC
- Officer in-charge of the MDS
- Pharmacist in-charge MDS
- Purchase Officer

3.4 Procedure

3.4.1 The demand for the drugs will be sent by the Officer in-charge of the MDS to the Purchase Officer.

3.4.2 In case of Emergency, the demand will be sent by the User Department through Officer in-charge MDS to the Purchase Department.

3.4.3 The Officer in-charge of the MDS will forward the demand to Purchase officer after verifying the non availability of the drugs with reasons and justification.

3.4.4 The purchase officer of the hospital will arrange the drugs through

- Local purchase
- Any other valid rate contract of Delhi Government hospital.
- Under General Financial Rules 145 & 146.

3.4.5 The Purchase Officer will take the approval from the Head of the Institute for procurement of drugs .

3.4.6 The drugs will be received and recorded by the MDS and issued to concerned user department.

3.4.7 For purchase of drugs made at odd hours, the concerned department will bring to the notice of person authorized by the Head of Institute for such purposes who will make the drugs available from authorized local chemist.

3.4.8 A detailed analysis and review of drugs procured through local purchase throughout the year must be made by the Hospital DTC, in consultation with the Officer in charge of the MDS. Reasons for local purchase must be analyzed and ways to decrease the same for future must be looked for.

3.5 Records

- Stock register of MDS
- Stock Register of User Department
- Local purchase records by the Purchase Department.
- Indent vouchers sent to Purchase departmen

3.6 Process Efficiency Criteria

- Decrease in the number of drugs procured through local purchase.
- Minimum time required to obtain drugs through local purchase.

3.7 Activities

- Review of timing of indents sent to the warehouse by Officer in-charge MDS

- Review of availability of drugs in the health facility by the DTC bi-annually.
- Review of the hospital EDL
- Review of the drug quantification process of the hospital

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Department:	PHARMACY	SOP	4
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for receiving of drugs

4.1 Purpose

To ensure that the drugs are received by the hospital as per indent in appropriate specifications and quantity.

4.2 Scope

All activities concerned with ensuring proper receiving of drugs indented by the health facility.

4.3 Responsibility

- Officer in-charge MDS
- Pharmacist in-charge MDS

4.4 Procedure

4.4.1 All the drugs received in MDS of the health facility must be verified by the Officer in-charge MDS and Pharmacist in-charge MDS as per indent. The drugs must be checked for their

- Physical appearance
- Quantity
- Number,
- Expiry date
- “Hospital Supply NOT for sale” Logo.

The same should be recorded in the Stock register.

4.4.2 At the time of receiving of drugs, if the drugs do not appear in appropriate physical conditions then the drugs should not be accepted. These should be sent back to warehouse / Supplier. The same may be informed to Purchase Officer and the Head of the Institute.

4.5 Records

- Stock register of MDS

4.6 Process Efficiency Criteria

- Receiving of appropriate drugs in appropriate quantity & quality at all times.

4.7 Activities

- Random checking of the drug entries in the stock register and verifying with the indent vouchers /Challan/Invoice.

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Department:	PHARMACY	SOP	5
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for Storage of Drugs

5.1 Purpose

To provide guidelines for proper activities relating to storage of drugs.

5.2 Scope

- MDS, Sub Stores of respective Departments.
- Pharmacy (OPD).

5.3 Responsibility

- Officer in-charge of MDS.
- Pharmacist in-charge of MDS.
- Pharmacist's in-charge/Nursing Sister In-Charge of various department sub stores.

5.4 Procedure

5.4.1 All the drugs are to be stored as per the instructions mentioned on the label by the manufacturer . These should address issues pertaining to temperature (refrigeration), light, ventilation, preventing entry of pests/ rodents and vermin's) at all location of storage such as stores and pharmacy

5.4.2 Drugs shall be stored in a clean, well lit and ventilated environment.

5.4.3 There should be no direct sunlight in the area where the drugs are stored

5.4. 4 The storage areas should be free of vermin and pests.

5.4.5 Consistently monitor the temperature of the different areas within the storeroom. Keep thermometers in various places for monitoring.

5.4.6 Do not keep boxes on the floor directly. Keep on pallets with air space in between

5.4.7 The storage of drugs should be done preferably in alphabetical order of their generic names in all the areas.

5.4.8 Refrigerator used for storage of drugs should have a continuous temperature recording device like data logger and same should be documented. Refrigerator temperature shall be recorded ideally three times a day in the stores and in the pharmacy and the same shall be verified and counter signed by the in-charge staff.

5.4.9 Drugs should be stored in a manner to avoid pilferage and theft by installing CCTV at strategic locations.

5.4.10 All look alike, sound alike drugs should be stored separately in all the areas.

5.4.11 Inventory practices (like first in and first out (FIFO, ABC, VED) shall be followed while issuing inventory.

5.4.12 Records of the drugs in all storage areas should be maintained preferably in electronic mode.

5.5 Process Efficiency Criteria

a) All the drugs are to be stored as per manufacturer's instructions on the label.

5.6 Process Activity

b) Audits and physical verification at regular intervals of all the storage areas by a committee constituted by Head of the Institution.

References

c) Drugs and Cosmetics Act,1940
d) Drugs and Cosmetics Rules, 1945.
e) Delhi Narcotic Drug Rules, 1985
f) Pharmacy Act, 1948
g) NABH: Pre Accreditation Entry Level Standards For Hospitals, April 2014
h) World Health Organization: Guidelines for storage of essential medicines and other health commodities, 2003.

Definitions

a) Protect from moisture: Store the product in a space with no more than 60% relative humidity.

b) Store frozen: Store products at -20 degree C (4 degree F)

c) Store at 2-8 degrees C (36- 46 degree F) : These are usually kept in the first and second part compartment of the refrigerator (never the freezer)

d) Cool Place: Store between 10 degree C and 25 degree C

e) Cold Place: Store at a temperature not exceeding 8 degree C

f) *Store at ambient temperature:* Store at the surrounding temperature. This term is not widely used due to significant variation in ambient temperatures. It means "room temperature" or normal storage conditions, which means storage in a dry, clean, well ventilated area at room temperatures between 15 to 25 degree C or up to 30 degree C, depending on climatic conditions.

g) Whenever storage condition is not specified store at room temperature.

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Department:	PHARMACY	SOP	6
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for maintenance of temperature of pharmaceutical refrigerators/ deep freezer/ ice-lined refrigerator

6.1 Purpose

To ensure that drugs are stored at appropriate temperature in the hospital.

6.2 Scope

All activities related to storage of drugs at appropriate temperature required in pharmaceutical refrigerator/deep freezer/ ice-lined refrigerator.

6.3 Responsibility

- Pharmacist in- charge of MDS
- Pharmacist in- charge of pharmacy(OPD)
- Nursing Sister in charge of IPD sub-stores & OPD sub-stores

6.4 Procedure

6.4.1 The temperature of all electrical cold chain equipment (pharmaceutical refrigerator / deep freezer, ice-lined refrigerator) should be recorded at least thrice daily i.e. opening, closing time of drug store and once midway.

6.4.2 Pharmacist in-charge of MDS , Sister in-charge of sub-stores of various departments of the hospital will sign the record and the same should be randomly checked by Officer in-charge.

6.4.3 Continuous power supply must be ensured for maintenance of the temperature by suitable electricity backup.

6.4.4 In case of non-maintenance of temperature, the pharmacist or nursing sister in-charge should immediately intimate the same to concerned Officer in-charge of the department. They will also inform immediately to Institution Repair Maintenance Department, Electrical Department, Supplier of the equipment in case of equipment being in the warranty period or with Annual maintainer contract .

6.4.5 The drugs stored in the non-functioning refrigerator must be shifted to alternative pharmaceutical refrigerators.

6.4.6 In case drugs have been stored at sub-optimal temperature for an inappropriate time this information must be brought to the notice of Officer in-charge of MDS & concerned unit in-charge. Such drugs must be returned back to MDS for disposable.

6.4.7 Proper records of drugs which have not been stored at the temperature required for the duration specified by the manufacturer, must be maintained.

6.4.8 Placing of refrigerators

Place refrigerators and freezers with space between and about an arm's length away from the wall. This will increase air circulation. Ideally rooms with multiple refrigerators and or freezers should have air conditioning. If it is not possible to have air conditioning , install fans around the equipment to increase airflow. Ideally, larger facilities should have a cold room rather than numerous refrigerators.

6.5 Records

- Temperature log book.
- Temperature charts.
- Record of drugs that could not be used due to inadequate temperature maintenance of the refrigerators

6.6 Process Efficiency Criteria

- Maintenance of appropriate temperature in the refrigerator at all times.
- Minimal wastage of drugs due to improper storage of drugs .

6.7 Activity

- Review of temperature maintenance process and records of the refrigerators at regular intervals.
- Review of records of drugs that may have been disposed off due to improper storage.

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Department:	PHARMACY	SOP	7
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure of indenting drugs to the patient care area

7.1 Purpose

To develop documented procedures for indenting drugs to the patient care area.

7.2 Scope

All the activities related to indenting drugs for OPD patients, Emergency & IPD patients.

7.3 Responsibility

- Officer in-charge of MDS
- Pharmacist in-charge of MDS
- Officer in-charge of OPD Pharmacy
- Pharmacist in-charge of OPD Pharmacy
- Nursing Sister in- charge of concerned department/unit sub-stores.

7.4 Procedure

7.4.1 The indent of drugs from concerned departments will be placed, preferably every fifteen days by the Pharmacy and monthly by the inpatient departments to the MDS. In case of any exigency, supplementary indents can also be placed with proper justification.

7.4.2 Pharmacist in-charge /Sister in-charge of concerned departments / units, will assess the quantity of drugs required, on the basis of consumption pattern and stock in hand on indent books of respective departments/unit. Two copies of the same will be made and signed individually.

7.4.3 The officer in-charge of Pharmacy/concerned department, unit will verify the list of drugs prepared with addition/deletions required, if any.

7.4.4 The list of drugs to be indented must be signed by Pharmacist in-charge/ Sister in-charge and the Officer in-charge of the pharmacy/departments/unit.

7.4.5 The the list of drugs will be forwarded to Officer in-charge MDS for his/her signature, who will direct the Pharmacist in-charge of the MDS to issue the drugs to the pharmacy/ department/unit.

7.4.6 The Pharmacist in-charge of the drug stores will issue the drugs to the concerned department .

7.4.6.1 The Pharmacist in-charge will verify at the time of issuing, the quantity of drugs issued to the department in the last indent as per his stock records as well as the availability in the MDS .

7.4.6.2 The Pharmacist in-charge will mention the quantity of drugs issued to the department on the indent voucher of the department. One copy of the indent voucher will be retained by the MDS and another copy will be given to the pharmacy or respective department sub-stores for record keeping.

7.4.6.3 Signatures of both officials of the indenting and receiving departments will be affixed on both the copies of indent vouchers.

7.4.7 Both the Pharmacist in-charge of the drug stores as well as the Pharmacist in-charge of OPD Pharmacy / Nursing Sister in-charge of concerned departments will ensure that at the time of reception of goods from the MDS, the same are checked for quantity, batch number, expiry date, damages and contamination, if any.

7.4.8 The Pharmacist in-charge of the MDS stores as well as the Pharmacist in-charge of OPD Pharmacy/Nursing Sister in-charge of concerned department sub-stores will then make necessary entries in their respective stock registers.

7.4.9 The MDS will make a schedule of days and time for different departments for collecting indent to reduce overcrowding at the MDS.

7.5 Records

- Stock Registers of MDS, OPD Pharmacy & department sub-stores.
- Indent books of OPD Pharmacy & departments/units.
- Copy of the Indent book vouchers by the MDS.

7.6 Process Efficiency Indicators

- Minimal stock out of medicines from OPD Pharmacy and concerned department sub-stores.
- Placing of Indents by OPD Pharmacy & concerned departments as per schedule.
- Issuing of Indents by the MDS as per schedule.
- Number of times the stock of specific drug goes down below designated re-order level.

7.7 Activities

- Review of drug stocks in MDS
- Review of drug stocks in stores of OPD Pharmacy & department sub- stores.

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Department:	PHARMACY	SOP	8
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for issue of drugs in Emergency conditions

8.1 Purpose

To have a mechanism to ensure that the drugs for emergency conditions are readily available at all times.

8.2 Scope

All the activities involving issue of drugs in emergency conditions in Emergency and other IPD areas.

8.3 Responsibility

- DTC
- Officer in-charge MDS
- Nursing Sister in-charge and other nursing staff of concerned departments
- Purchase Officer.

8.4 Procedure

8.4.1 DTC of the hospital will prepare the list of emergency conditions for which drugs may be required. The DTC will specify the list of drugs required for the same.

8.4.2 All drugs for emergency conditions will be available in the Emergency and all IPD areas of the hospital .

8.4.3 All In-patient areas should maintain an inventory of drugs for emergency conditions, which should be readily available, along with their expiry dates.

8.4.4 All drugs for emergency conditions used shall be replenished by the nurse on duty immediately after use with each case.

8.4.5 Drugs inventory will be checked by the nurse on duty with each shift change, to detect loss or pilferage.

8.4.6 Narcotics drugs shall be kept in the designated safe area and will be under the supervision of the Nurse in-charge.

8.4.7 Narcotic drugs will be released only on the signed requisition of the consultant/Medical Officer. All guidelines related to use of narcotic drugs should be strictly followed.

8.4.8 In case of rare emergency conditions for which emergency drugs are not available in emergency drug list, the same should be made available by Hospital administration as per SOP for local purchase of drugs.

8.5 Records

- List of emergency conditions and drugs required for the same made by the DTC of health facility.
- Stock registers of drugs for emergency conditions in Emergency & all IPD areas.

8.6 Process Efficiency indicators

- Availability of drugs for emergency conditions at all times in the Emergency and all IPD areas.

8.7 Activities

- Daily review of drugs for emergency conditions available by the Nursing Sister in-charge or nurse on duty of all departments.

****

List of drugs used in emergency conditions*

S. NO.	DRUG	INDICATION
1	Adenosine	Supra-ventricular tachycardia
2	Aminophylline	Asthma
3	Amiodarone	Arrythmias
4	Anti-rabies vaccine	Dog bite, Rabid Animal bite
5	Anti-snake Venom	Snake bite
6	Atropine	Bradycardia, Asystole
7	Calcium gluconate	Hyperkalaemia, Hypocalcaemia, Calcium Channel Blocker Toxicity
8	Charcoal	Poisoning, Gastric Lavage
9	Dexamethasone Sodium	Asthma, Allergic conditions
10	Diazepam	Seizures
11	Diclofenac sodium	Pain
12	Dicyclomine	Antispasmodic
13	Dobutamine	Heart failure
14	Dopamine	Cardiogenic shock
15	Enoxaparin	Myocardial Infarction, Unsatble angina, Deep Vein Thrombosis
16	Epinephrine/ Adrenaline	Cardiac arrest, Anaphylaxis
17	Furosemide	Pulmonary oedema, Diuresis
18	Glucagon	Hypoglycaemia
19	Glucose	Hypoglycaemia
20	Haloperidol	Seizures, Psychosis
21	Heparin sodium	Myocardial Infarction, Deep Vein Thrombosis
22	Hydrocortisone sodium	Asthma, Shock, Anti-Inflammatory
23	Hyoscine Butyl Bromide	Antispasmodic
24	Insulin	Diabetes mellitus, Diabetic ketoacidosis
25	Lorazepam	Seizures, Status Epilepticus
	Magnesium Sulphate	Arrythmias, hypomagnesaemia
	Methylergometrine Maleate	Stop hemorrhage from the uterus
27	Morphine sulphate	Myocardial Infarction, Left ventricular failure
28	Naloxone	Opioid overdose
29	Nitro-glycerine	Angina, Hypertensive emergency
30	Nor-Epinephrine/ Nor-Adrenaline	Hypotension, Shock
31	Ondansetron	Anti-emetic
32	Oxygen	Asthma, Myocardial Infarction
33	Oxytocin	Inducing labor
34	Paracetamol	Fever
35	Pheniramine maleate	Allergic reactions, Insect bite
36	Phenylephrine	Hypotension
37	Phenytoin	Seizures, Anticonvulsant
38	Pralidoxime Chloride (PAM 2)	Organophosphate poisoning

39	Rabies Immunooglobulin	Dog bite, Rabid Animal bite
40	Salbutamol	Asthma
41	Sodium Nitroprusside	Hypertensive emergency
42	Streptokinase	Myocardial Infarction, Pulmonary embolism
43	Tetanus immune globulin	Tetanus prophylaxis, Active tetanus treatment
44	Tetanus toxoid	Tetanus prophylaxis
45	Tramadol	Pain
46	Valproic Acid	Seizures
47	Verapamil	Supra-ventricular tachycardia
48	Vitamin B_{12}	Anaemia, Alcoholism
49	Vitamin K	Haemorrhagic conditions

* This list is not complete. It contains some drugs that may be included in the list of emergency drugs. The DTC of the health facility will decide the drugs to be included in the list of emergency drugs**.**

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Department:	PHARMACY	SOP	9
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for maintaining near expiry drugs at store and pharmacy

9.1 Purpose

To establish a procedure for identifying, handling and maintaining the near-expiry medications in MDS, departmental sub-store and Pharmacy (OPD) with a view to minimize loss and ensure patient safety.

9.2 Scope

All the important activities related to handling of near expiry drugs in the health facility at all levels.

9.3 Responsibility

- Officer in-charge MDS
- Pharmacist in--charge of MDS
- Sister in-charge of various departments of the hospital.
- Pharmacist in-charge of Pharmacy (OPD).

9.4 Procedure

9.4.1 All drugs delivered to the hospital must carry an " Expiry date" which must be recorded in the stock register by Pharmacist in-charge of MDS.

9.4.2 At the time of reception of drugs by the concerned department and Pharmacy (OPD), Expiry date of drugs must be checked by the Pharmacist in-charge /Nursing sister in-charge of various sub-stores of the hospital.

9.4.3 The MDS, Pharmacy (OPD) and all other department sub-stores must follow First in-First out system of inventory management to minimize the stock of near expiry drugs, except in cases where the stock received later have a shorter expiry date.

9.4.4 MDS, Pharmacy (OPD) and department sub-store in-charges must arrange the drugs which will expire in next 3 months, on separate shelves.

9.4.5 All efforts must be made by concerned Pharmacist in-charge, Nursing sister in-charges of all departmental sub-stores to see that drugs found to be of near expiry can be transported to other departments i.e. intra &inter departments for utilization of the drugs within their expiry date.

9.4.6 If near expiry drugs are not in a position to be consumed, in that way they should be sent to MDS.

9.4.7 If the item is urgently needed and there is no replacement stock in Pharmacy (OPD) and MDS then the Nursing sister in-charge can use it until last day of expiry.

9.4.8 When the near expiry drugs are received at MDS then the officer in-charge MDS must be informed about the near expiry drugs who in turn may explore either of the following:-

- Inter-departmental transfer
- Transfer to other hospital
- Transfer to District Store
- Transfer to CPA/Corporation
- Drug replacement from the manufacturer / supplier for fresh stock

It will be advisable for all Hospitals under Delhi Government to procure, install and use a **Hospital Management Information System (HMIS)** having proven efficiency to minimize the loss to the Government exchequer due to expiry of drugs. This will also be useful in identifying, at the click of a button, the drugs which are approaching their date of expiry so that they can be got replaced from the manufacturer/supplier or can be consumed within the Hospital or another Government Hospital with a view to avoid wastage.

9.5 Records

- Near Expiry stock of drugs must be recorded in the stock register of the particular department, ward or Pharmacy as the case may be.

9.6 Process efficiency criteria

- The number of drugs nearing expiry must be minimal and should show a declining trend with time.

9.7 Activity

- Monthly inspections must be conducted by the concerned pharmacist and nursing staff of respective departments.
- Annual review by the DTC to assess the number of drugs reaching near expiry and actions taken thereof during the year

9.8 References

- Drugs & Cosmetics Act, 1940.
- Drugs & Cosmetics Rules, 1945.
- The Pharmacy Act, 1948.

9.9 Definitions

- **Expiry Date** means the date that is recorded on the container, label, or wrapper as the date up to which the substance may be expected to retain a potency not less than or not to acquire a toxicity greater than that required or permitted by the prescribed test. The date of expiry of a product as assigned by the manufacturer is at times expressed only in month and year, which means that the product is to be used until the last day of the given month for that year.
- **Near-expiry Drugs** refers to drugs, the efficacy of which is about to lapse within 3 months from the expiry date printed on the label by its manufacturer.

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Department:	PHARMACY	SOP	10
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for disposal of expired drugs

10.1 Purpose

To establish a procedure for the segregation and disposal of expired drugs in hospital.

10.2 Scope

All activities required for disposal of expired drugs in the hospital.

10.3 Responsibility

- Officer in-charge MDS
- Pharmacist in-charge MDS
- Officer in-charge Pharmacy (OPD),
- Pharmacist in-charge Pharmacy 9OPD)
- Officer in-charge of Unit/ward
- Nursing Sister in-charge of Unit/ward
- DTC
- Officer in-charge Bio-Medical Waste Management of Hospital

10.4 Procedure

10.4.1 All the expired drugs from various areas/departments should be returned to MDS of the hospital with proper documentation.

10.4.2 The information about expired medicines must be recorded in a separate register for expired drugs. The following particulars are to be documented:-

- Name of drug (Generic/brand)
- Formulation (Tablet/Capsule/Syrup/ Ointment/Injection etc.)
- Strength
- Batch number
- Expiry date
- Total quantity
- Name of the department

10.4.3 At the MDS the expired drugs must be received by the Pharmacist in-charge. He must verify the details and the drugs record as given in Para 6.4.2.

10.4.4 All expired drugs should be stored preferably in a separate room ear marked for the purpose. In the absence of a separate room the expired drugs may be stored in a separate cupboard. The cupboard must always be under lock and key with a sign board on it stating "**Expired drugs not for use**''. The room / cupboard must be under supervision of Officer in-charge/ Pharmacist in-charge of MDS.

104.5 The Officer in-charge MDS will inform the DTC about the details of the expired drugs for their disposal.

10.4.6 After approval from DTC the Officer in-charge MDS will inform the Head of Institute/ Medical superintendent, about the list of expired drugs to be sent for disposal to Bio-Medical Waste In-charge.

10.4.7 The Officer in-charge MDS will send this list to hospital Bio-Medical Waste in-charge for disposal as per rules.

10.4.8 All the expired drugs must be transported in pilfer proof containers/boxes properly labeled and sealed in accordance with prevailing Bio-Medical Waste Management Rules.

The hospital DTC will regularly meet and assess the list of expired drugs and reasons for the same.

10.5 Records

- Expiry drug register in sub-stores of unit/wards/ departments.
- Expiry drug register in Pharmacy (OPD)
- Expiry drug register at MDS.
- Drug disposal register at Bio-Medical Waste Management Department.

10.6 Process Efficiency Criteria

- The number of expired drugs in a hospital should ideally be nil or minimal.
- Within a hospital the number of expired drugs annually must decrease over time.

10.7 Activity

- Review of expired drugs by DTC at regular interval (at least annually).

Form for list of expired drugs and label for disposal

1) **List of expired drugs**

S. No.	Name	Formulation*	Strength	Batch No.	Expiry Date	Quantity	Name of Department, Unit, Ward etc.	Unit/Ward No.

*Formulations include dosage form.

Signature of Officer In-charge Unit/Ward/OPD Pharmacy/Casualty

Signature of Nursing Sister In-charge of Unit/Ward/OPD Pharmacy/Casualty

Stamp

2) **Label for transfer of expired drug**

Date……

Category of drug……

Bio-hazard symbol…….

3) BIO MEDICAL WASTE CATEGORIES

SCHEDULE I

Biomedical wastes categories and their segregation, collection, treatment, processing and disposal options

Category Type of Waste Type of Bag or Container to be used Treatment and Disposal options (1) (2) (3) (4)

Category	Type of Waste	Type of Bag or Container to be used	Treatment and Disposal options
1	2	3	4
YELLOW	**(a) Human Anatomical Waste:** Human tissues, organs, body parts and fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time).	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial*
	(b) Animal Anatomical Waste : Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in veterinary hospitals or colleges or animal houses.		
	(c) Soiled Waste:		Incineration or Plasma

	Items contaminated with blood, body fluids like dressings, plaster casts, cotton swabs and waste to be sent for energy recovery.		Pyrolysis or deep burial* In absence of above facilities, autoclaving or micro-waving/ bags containing residual or discarded blood and blood components. hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery.
	(d) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.	Yellow coloured non-chlorinated plastic bags or containers	Expired `cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the manufacturer or supplier for incineration at temperature >1200°C or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >1200°C Or Encapsulation or Plasma Pyrolysis at >1200°C. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.
	(e) Chemical Waste:	Yellow coloured containers or non-	Disposed of by incineration or Plasma

	Chemicals used in production of biological and used or discarded disinfectants.	chlorinated plastic bags	Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.
	(f) Chemical Liquid Waste : Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X-ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids**,** liquid from laboratories and floor washings, cleaning, house-keeping and disinfecting activities etc.	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms given in Schedule-III.
	(g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.	Non-chlorinated yellow plastic bags or suitable packing material	Non- chlorinated chemical disinfection followed by incineration or Plasma Pyrolysis or for energy recovery. In absence of above facilities, shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery or incineration

			or Plasma Pyrolysis.
	(h)Microbiology, Biotechnology and other clinical laboratory waste: Blood bags, Laboratory cultures, stocks or specimens of microorganisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial laboratories, production of biological, residual toxins, dishes and devices used for cultures.	Autoclave safe plastic bags or containers	Pre-treat to sterilize with nonchlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines thereafter for Incineration.
RED	**Contaminated Waste** **(Recyclable)** (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and *fixed needlesyringes*) and vaccutainers with their needles cut) and gloves.	Red coloured non-chlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.

WHITE **(TRANSLUCENT)**	**Waste sharps including Metals:** Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, Leak proof, tamper proof containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit.
BLUE	**(a) Glassware:** Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.	Cardboard boxes with blue colored marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.
	(b) Metallic Body Implants	Cardboard boxes with blue colored marking	

Part -2

(1) All plastic bags shall be as per BIS standards as and when published, till then the prevailing Plastic Waste Management Rules shall be applicable.

(2) Chemical treatment using at least 10% Sodium Hypochlorite having 30% residual chlorine for twenty minutesor any other equivalent chemical reagent that should demonstrate Log104 reduction efficiency for microorganisms as given in Schedule- III.

(3) Mutilation or shredding must be to an extent to prevent unauthorized reuse.

(4) There will be no chemical pretreatment before incineration, except for microbiological, lab and highly infectious waste.

(5) Incineration ash (ash from incineration of any bio-medical waste) shall be disposed through hazardous waste treatment, storage and disposal facility, if toxic or hazardous constituents are present beyond the prescribed limits as given in the Hazardous Waste (Management, Handling and Transboundary Movement) Rules, 2008 or as revised from time to time.

(6) Dead Fetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time) can be considered as human anatomical waste. Such waste should be handed over to the operator of common bio-medical waste treatment and disposal facility in yellow bag with a copy of the official Medical Termination of Pregnancy certificate from the Obstetrician or the Medical Superintendent of hospital or healthcare establishment.

(7) Cytotoxic drug vials shall not be handed over to unauthorized person under any circumstances. These shall be sent back to the manufactures for necessary disposal at a single point. As a second option, these may be sent for incineration at common bio-medical waste treatment and disposal facility or plasma pyrolysis at temperature >1200 0C.

(8) Residual or discarded chemical wastes, used or discarded disinfectants and chemical sludge can be disposed at hazardous waste treatment, storage and disposal facility. In such case, the waste should be sent to hazardous waste treatment, storage and disposal facility through operator of common bio-medical waste treatment and disposal facility only.

(9) On-site pre-treatment of laboratory waste, microbiological waste, blood samples, blood bags should be disinfected or sterilized as per the Guidelines of World Health Organization or National AIDS Control Organization and then given to the common bio-medical waste treatment and disposal facility.

(10) Installation of in-house incinerator is not allowed. However in case there is no common biomedical facility nearby, the same may be installed by the occupier after taking authorisation from the State Pollution Control Board.

(11) Syringes should be either mutilated or needles should be cut and or stored in tamper proof, leak proof and puncture proof containers for sharps storage. Wherever the occupier is not linked to a disposal facility it shall be the responsibility of the occupier to sterilize and dispose in the manner prescribed.

(12) Bio-medical waste generated in households during healthcare activities shall be segregated as per these rules and handed over in separate bags or containers to

municipal waste collectors. Urban Local Bodies shall have tie up with the common bio-medical waste treatment and disposal facility to pickup this waste from the Material Recovery Facility (MRF) or from the house hold directly, for final disposal in the manner as prescribed in this Schedule.

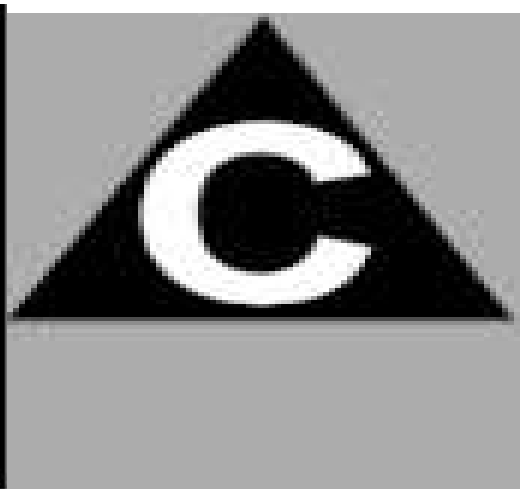
SCHEDULE IV

Part A

LABEL FOR

BIO-MEDICAL WASTE CONTAINERS or BAGS

CYTOTOXIC HAZARD SYMBOL



HANDLE WITH CARE

HANDLE WITH CARE

Part B

LABEL FOR TRANSPORTING BIO-MEDICAL WASTE BAGS OR CONTAINERS

Day .....

Month .....

Year .....

Date of generation .....

Waste category Number .....

Waste quantity……

Sender's Name and Address Receiver's Name and Address:

Phone Number ..... Phone Number .....

Fax Number..... Fax Number .....

Contact Person ..... Contact Person .....

In case of emergency please contact :

Name and Address :Phone No.

Note :Label shall be non-washable and prominently visible.

Department:	PHARMACY	SOP	11
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for rational use of drugs

11.1 Purpose

To establish a procedure for rational use of drugs received by patients in the health facility.

Wherein rational use of drugs requires that patients receive drugs appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community (hospital and Government).

11.2 Scope

All patient care areas in the health facility, hospital including various departments, IPD, Emergency and OPD.

11.3 Responsibility

- Head of Institute/ Medical Superintendent
- DTC
- Head of departments
- Consultants of various departments
- Resident doctors
- Nursing Sister in-charges/ staff nurses
- Pharmacists

11.4 Procedure

11.4.1 All processes involved in selecting, procuring, storing, distributing, dispensing, prescribing, administering the drugs must be based on rational and scientific standard guidelines.

11.4.2 Each hospital must have a 1) **Drug Therapeutics Committee (DTC),** The committee will develop policies for ensuring and monitoring rational use of drugs within the health facility.

11.4.3 The Head of the Institute will constitute the DTC

11.4.4 Structure and Organisation of DTC

All Committees should have sufficient members to represent all stakeholders, including the major clinical departments, the administration and pharmacy.

Members should be selected with reference to their positions and responsibilities.

The DTC shall comprise of the following members

1) Chairman : A senior doctor may be appointed as the Chairman
2) Secretary: The Committee Secretary may be the pharmacist or any other member of the Committee can be appointed as the secretary.
3) Members: The other members will be on a representational basis. A representative clinician from each major specialty, including departments of Internal Medicine, Surgery, Pediatrics, Gynecology & Obstetrics, any other department as the health facility considers essential to improving the working of the DTC.
4) Clinical Pharmacologist, wherever available
5) Clinical Microbiologist or a laboratory technician when there is no microbiologist available
6) Pharmacist (Chief or deputy)
7) Nurse (Senior nurse /matron)
8) An administrator representing the hospital administration & finance department.
9) A member of the hospital records department

Note: All members may not be available within smaller health facilities. To begin with the DTC may function with a suitable alternative available, till as such an arrangement can be worked out to provide the same.

It is advisable that in the initial years the Head of Departments may be included as members, from whom the Chairperson will be designated.

The DTC shall meet regularly , preferably at least every quarter.

11.4.5 **Pre requisite:** All the members of the DTC must give a Declaration that they have no Conflict of Interest with the assigned work in the DTC, especially that related to selecting the essential medicines list for the hospital, especially medicines which are not there in the main list of the Government.

11.4.6 **Meetings :**The DTC must have regular meetings. The number and time will depend on the work and terms of reference. The DTC must keep a record of all minutes of the meetings held. The DTC will be in direct communication with the Medical Superintendent. The quorum of the DTC will be fixed by the Head of the Institute.

11.4.7 **Role of DTC-**

- To develop and manage the hospital EDL.
  DTC will be responsible for selection of effective, safe, high quality, cost-effective medicines for the health facility's EDL .The DTC will formulate it's own EDL from the main list issued by the Government of Delhi
- In case there are some drugs which the DTC considers essential for use within their health facility, the same may be included in the list.
- The DTC will have to give justification for inclusion of drugs which are not there in the main list. Reasons for the same must be recorded. Selection of drugs must be based on

scientific evidence, keeping the four cardinal principals of efficacy, safety, suitability and cost of medicine in mind.

- To increase awareness amongst all concerned about the EDL of the health facility.

The DTC will formulate strategies to ensure that all doctors, pharmacists and nurses working within the health facility are aware about the list of drugs available within their health facility.

- To assess reasons for non availability of essential drugs within the hospital

The DTC will assess the drugs which are not available and the possible reasons for it. Solutions for local problems must be resolved by discussion and put in writing. Feasibility of implementing

these within the health facility must be explored.

- Formulate policies for improving rational use of drugs within the health facility.
- Formulate policies and processes for prudent use of antimicrobials within the facility
- Monitoring adverse drug reactions and medication errors.
- Increased staff and patient knowledge about drugs
- Advise in medicine procurement and inventory management.
- Advise in management of pharmaceutical expenditures
- Monitoring and identification of problems relating to use of drugs in the facility.

11.4.8 The DTC will liaison with the hospital Infection Control Committee, with the Purchase department and Hospital Stores.

11.9 Records

- Record of minutes of meetings of DTC
- The list of selected essential drugs required for the health facility

11.10 Process Efficiency Criteria

The outcomes as related to use of drugs in the health facility must improve. These include :-

- Availability of essential drugs
- Indicators for rational prescribing
- Improved patient knowledge about medicines
- Improved dispensing
- Less wastage of drugs
- Expenditure incurred on drugs

11. 11 Activity

- Regular prescription audits by the DTC
- Review of availability of drugs within the health facility
- Review of the number of drugs procured through local purchase
- ABC analysis of expenditure incurred on drugs
- Random checks to assess for quality of drugs
- Random surveys to assess for patient knowledge about drugs

Reference

Drug & Therapeutics Committee. World Health Organization and Management Sciences for Health. Geneva ,WHO 2006

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Department:	PHARMACY	SOP	12
Division:	IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for rational prescribing

13.1 Purpose

To provide guidelines for rational prescribing by the doctors.

12.2 Scope

All activities related to prescribing of medicines in the OPD and IPD

12.3 Responsibility

- Head of the institute
- DTC
- All doctors

12.4 Procedure

12.4.1 Prescriptions will only be written by qualified medical practitioners working within the health facility

12.4.2 Prescriptions will be written in a format as prescribed by MCI

12.4.3 All prescriptions must be written in ink.

12.4.4 All prescriptions must be legible, complete(details given below) and rational

12.4.5 The patients examined by the doctors are to be prescribed only the medicines required by that particular patient appropriate to his / her clinical needs, in doses that meet their individual requirement, for an adequate period of time.

12.4.6 There must be printed forms/cards for prescription writing supplied by the health facility. Each should have all the information as specified in the prescription form specified by MCI

The following must be printed with enough space for the doctors to write

Doctors details

- Name of doctor…….
- Designation of doctor……
- Date and time……..
- Signature…….
- Stamp……..

Patient details

- Patient's ID number……..
- Patient's name…….
- Address
- Age and weight of pediatric patients

Date of prescription

Details of treatment.

- Name of medicine (GENERIC)
- Dosage regimen- strength/amount, frequency of administration/ duration/ Total number of units or quantity of dosage forms required
- Directions for use
- The details of drugs/medicines prescribed are to be written in CAPITAL letters only

- Drugs must be prescribed using generic names only. In case a patient requires a specific brand of a drug, then the generic name must be written first followed by the brand name within brackets

Dispensing Pharmacist Details

- Name
- Name of Pharmacy
- Location
- Signature

12.4.7 The medical practitioner shall sign each prescription and put her/his stamp below it

12.4.8 **NO abbreviations** must be used. This includes for names of drugs, units or weights, frequency of administration (E.g. “Units” must be written in full and not abbreviated to “U”. “Microgram” must be written in full and not abbreviated to “mcg” or “ug”. “Six hourly” must be written in full and not abbreviated to “6/24., TDS, BD OD must not be used. Instead the frequency should be written as once a day, twice a day.

12.4.9 Prescriptions must be written in a way that the patient or his attendant can also understand . No Latin terms must be used

12.4.10 Patients must be explained the prescription written for them, in a way that they are able to understand. To check that they have understood the prescribing instructions clearly they must be asked to repeat the instructions back to the doctor.

12.5 **Inpatient records**

The principles written above also apply to inpatient records of patients

12.5.1 In the case of inpatients the doctor who visits the patients during rounds in the patient's hospital room may advise medications which should be written down in the drug order sheet in the patients file. This order/prescription should also be legibly written with details regarding dose, duration, mode and frequency of administration etc. and duly signed by the doctor with date, time. The ward staff will procure these medicines from the pharmacy and keep it separately for each patient. These medicines should be administered according to the doctor's orders by the nursing staff to the inpatients.

12.5.2 Whenever there is doubt regarding a particular prescription (such as illegible handwriting, wrongly written strength/dose or frequency, doubt regarding similar sounding medicines, duplication etc) or when a prescription is incomplete (without sign, date, etc), the junior doctor/pharmacist /nurse shall promptly call the Doctor and get it corrected without causing inconvenience for patient.

12.5.3 The attending nurse shall remind the treating doctor about the patients known drug allergies as marked with red ink on the patients file so that the patient does not receive that drug.

12.5.4 When the patients are discharged the remaining medicines shall be handed over to the patients/relatives and they must be instructed on how to use them at home. They must be prescribed appropriate amount of drugs till their next visit to the health facility.

12.6 Verbal orders:

12.6.1 In the case of in patients, in emergency situations if the doctor gives any verbal orders or telephonic orders regarding medicines to be administered to a particular patient. The individual accepting the verbal order shall record and then read back the

order in its entirety to the prescribing physician at the time the order is given, documenting that the order was “read back” (RB).

12.6.2. Nursing staff shall tag all verbal orders with a “SIGN HERE & DATE” tag to alert the physician of the need to sign the verbal order upon return to the unit.

12.6.3 Nursing staff are permitted to act upon verbal orders provided the orders contain the appropriate information.

12.4.4 Verbal and telephone orders shall be signed or initialed by the prescribing practitioner as soon as possible, not later than 24 hours.

12.6.5 When the ordering physician is unavailable, it is acceptable for another team member or the attending staff to authenticate the verbal order.

12.7 Records

- Prescription records of OPD
- IPD records
- Medico-legal records of Emergency Departments

12.8 Process efficiency criteria

- The prescription should have minimum number of drugs prescribed for a particular disease.
- All prescriptions should be complete (ie have all required information written)
- All prescriptions should be legible (be readable)
- All prescriptions should be rational

12.9 Activity

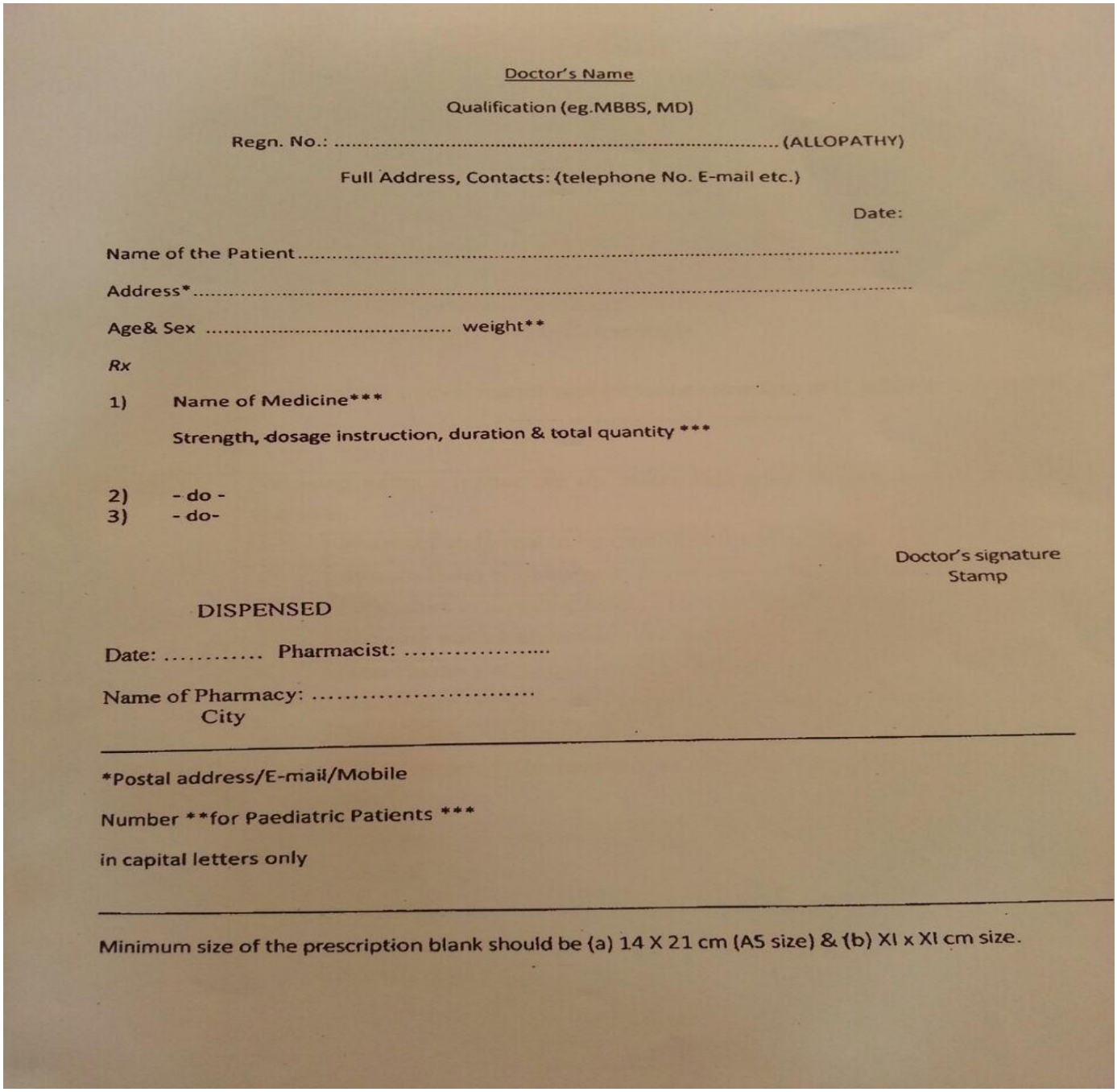
- Regular audits of prescriptions of IPD and OPD patients.

12.10 References

NABH: Pre Accreditation Entry Level Standards for Hospitals, April 2014

Form

MCI Standard prescription format



Doctor's Name

Qualification (eg.MBBS, MD)

Regn. No.: ..... (ALLOPATHY)

Full Address, Contacts: (telephone No. E-mail etc.)

Date:

Name of the Patient.....

Address*.....

Age& Sex ..... weight**

Rx

1) Name of Medicine***

Strength, dosage instruction, duration & total quantity ***

2) - do -

3) - do-

Doctor's signature
Stamp

DISPENSED

Date: ..... Pharmacist: .....

Name of Pharmacy: .....
City

*Postal address/E-mail/Mobile

Number **for Paediatric Patients ***

in capital letters only

Minimum size of the prescription blank should be (a) 14 X 21 cm (A5 size) & (b) XI x XI cm size.

Department:	PHARMACY	SOP	13
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for dispensing of drugs at Pharmacy

13.1 Purpose

To establish procedure for drug dispensing in all Inpatient and Outpatient areas.

13.2 Scope

- Main Pharmacy (OPD)
- Distribution counters of indoor departments of the hospital

13.3 Responsibility

- Officer in-charge pharmacy (OPD)
- Pharmacist in-charge pharmacy (OPD)
- Pharmacist/Nurses in-charges of sub-store of all departments

13.4 Procedure

13.4.1 Dispensing of drugs is to be done by qualified Pharmacists in the main pharmacy (OPD) of the hospital. Drugs to inpatients may be dispensed by pharmacists / nurses**.**

13.4.2 Before dispensing the prescription shall be screened for appropriateness of drug, dose, and frequency, route of administration, therapeutic duplications, drug-drug interactions, allergies, and formulary status.

13.4.3 Expiry dates of the drugs should be checked prior to dispensing.

13.4.4 A label must be put on the dispensed medicine. At a minimum, labels must include the drug name, strength, frequency of administration, in a language the patient understands

13.4.5 At the time of dispensing, complete information regarding drug dispensed i.e. name, dose frequency, duration and specific instruction if any must be conveyed to the patient or his/her attendant.

13.4.6 It must be ensured that no expired, contaminated, poor quality drug is dispensed to the patients.

13.4.7 In case of any accidental dispensing of a defective product, it will be the responsibility of the Pharmacy Supervisor to identify and get back those medicines and document in Drug Recall Register.

13.4.8 Details of all the drugs dispensed must be recorded in the dispensing registers preferably electronically and should be signed by pharmacist in-charge Pharmacy(OPD) , daily.

13.4.9 The communication between the dispensing pharmacist with the patient or attendant must be pleasant. All efforts must be made to see that the patient/attendant has understood the prescribing information provided by the pharmacist.

13.4.9 Pharmacist/ Nurse shall verify the allowable dosage as per standard and prescription for high risk medicines before dispensing. Also special attention shall be paid to educate the patients while using high risk medicines by nursing staff.

134.10 The DTC of the health facility must make a list of high risk medicines which must be kept in the Pharmacy (OPD) and department sub stores for easy use by pharmacists and nurses.

13.5 Records

- Dispensing Registers of Pharmacy (OPD)
- Dispensing registers of IPD

13.6 Efficiency Criteria

- All drugs prescribed must be dispensed to every patient with adequate information and instructions related to the drugs.

13.7 Activity

- Random audit of prescriptions and interview of patients to check for number of medicines dispensed from the number of medicines prescribed
- Interview of patients outside the pharmacy to assess basic knowledge of prescribed medicines as regards intake

13.8 References

NABH: Pre Accreditation Entry Level Standards For Hospitals. April 2014

WHO- How to investigate Drug Use in Health facilities

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Department:	PHARMACY	SOP	14
Division:	IPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for medication administration

14.1 Purpose

To provide guidelines for safe medication administration to patients.

14.2 Scope

All IPD areas within the hospital

14.3 Responsibility

Doctors

Nurses

Pharmacists

14.4 Procedures

14.4.1 All medications shall be administered as ordered by the physician, by an authorized health care professional.

14.4.2 A Staff nurse posted is approved to administer medications to the patient as ordered by the physician. If the medical staff member authorized to administer the medication has questions concerning the physicians' order, he/she should consult the physician or pharmacist prior to administering the medication.

14.4.3 The individual who administers the medication is responsible for ensuring that the right medicine with right dose is administered to the right patient through the right route at the right time.

14.4.4 Drug name, dose and expiry date on the label shall be verified before administering to patient.

14.4.5 **Labeling of medication:** Already prepared medications shall be labeled with the name of the drug, dosage, timing, start date & time, sign of the personnel prior to preparation of the second medication, applicable only for parenteral drugs.

14.4.6 **Patient identification prior to administration:** The patient shall be verified by CR Number and Name prior to administration of the drug.

14.4.7 **Medication verification: T**he medication shall be checked by the administering personnel with respect to:

- Treatment orders
- General appearance of the medicine
- Medication name
- Dosage
- Frequency and time
- Expiry date on label

14.4.8 In case of verbal orders, the verification shall be done by 'read back' method.

14.4.9 In case of high risk medications, the verifications shall be done independently by at least 2 staff, either a nurse-nurse or nurse-doctor and documented.

14.4.10 **Dosage verification:** The dose of the medication to be administered shall be double checked by the nurse from the treatment orders and documented in the medication chart.

14.4.11 R**oute verification:** The route of administering the medication shall be double-checked by the nurse from the treatment orders and documented in the medication chart.

14.4.12 **Timing verification:** The timing / frequency of the medication to be administered shall be double-checked by the nurse from the treatment orders and documented in the medication chart

14.4.13 **Documentation of medication administration:** Documentation of medication administered should be done in printed cards meant for the purpose. The cards should be formatted to have specified sections for writing date, time, name of drug, dose, route

All the entries in the chart shall include the:

- Date of entry
- Name of medication
- Dosage
- Route of administration
- Timing
- Name and signature of the person who has administered the medication.

In case of infusions, it shall capture the start time, the rate of infusion end time.

14. 4 .14 **Self-administration of medication:** Self-administration of injectable drugs shall not be permitted in the Inpatient care areas.

14.5 Process Efficiency Criteria

No medication errors due to administration of wrong medication, wrong dose, wrong route, to the wrong person or wrong time.

14.6 Activity

Assessment of medication errors occurring in the hospital

14.7 Reference NABH: Pre Accreditation Entry Level Standards For Hospitals, April 2014

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Department:	PHARMACY	SOP	15
Division:	IPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure to monitor medicines after administration to patients

15.1 PURPOSE:

To ensure patient safety after the administration of medication by continuous monitoring, a system for monitoring the medication errors and adverse drug reactions.

15.2 SCOPE:

All Inpatient care areas

15.3 RESPONSIBILTY:

- All Doctors
- Nurses
- Pharmacists
- Other support Staff &
- DTC
- Administration personnel

15.4 Procedure

15.4.1 All patients shall be monitored after medication administration to verify that the medication is having the intended effect and also to detect any near misses, medication errors and adverse drug reactions.

15..4.2 Critical areas such as the ICU shall require close monitoring of the patient every hour or earlier as per the treatment requirements.

15.4.3 The monitoring shall be done through collaborative means involving the duty doctors and Nurses.

15.4.4 Medications, as well as dosages, shall be adjusted if required based on the observations.

15.4.5 The medication administered is noted in the medication chart by the nursing staff.

15.4.6 Thereafter, all the charts are maintained periodically to ensure that the medication is having the intended effect on the patient.

15.4.7 The different charts to be maintained are:

- Medication
- Temperature, Blood pressure and heart rate (TPR)
- Intake – Output
- Nurses' notes

15.4.8 Any variation in the patient condition during the monitoring is to be immediately notified to the concerned treating doctor either directly by the nursing staff or on duty doctors whichever is appropriate in the given setting.

15.5 Records

All patient records, - Medication, BP, pulse rate, respiratory rate, temperature, nurses notes, doctors notes

15.6 Reference :

NABH: Pre Accreditation Entry Level Standards For Hospitals, April 2014

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Department:	PHARMACY	SOP	16
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for Adverse Drug Reaction monitoring

16.1 Purpose

To ensure patient safety after the administration of medication creating a system for monitoring, reporting and analyzing the medication errors and adverse drug reactions.

16.2 Scope

All areas concerned with use and storage of drugs – IPD, OPD, Pharmacy(OPD), MDS

16.3 Responsibility

- All Doctors
- Nursing Staff
- Drug and Therapeutics Committee
- Pharmacists

16.4 Procedure for the Identification and Review of any Medication Errors

16.4.1 The inpatients who are administered different drugs need monitoring during their stay in the hospital. On notice of an unusual incident regarding a medication on duty nursing staff shall immediately report to the consultant or the Doctor on Duty.

16.4.2 All patients will be asked for any prior history of drug allergy

16.4.3. Patients with past history of drug allergies shall be identified. If a drug prone to produce allergic reactions has to be administered, it should be done with caution. A small test dose of the drug is given intra dermal and marked with time, if any drug allergy is noted the main dose administration is withheld and the doctor shall be informed.

16.4.4 Drug reactions shall be promptly identified and the concerned doctor should be promptly informed and remedial action is taken.

16.4.5 All events and actions taken should be recorded by the concerned nurses in the patient's case sheet and signed with date.

16.4.6 When Intra Venous (I.V) medications, blood transfusions, are given the nurse must be present along with the patient to monitor the progress or note any undue side effects. Starting and discontinuation of I.V medication shall be done by the treating nurse and the details should be noted in the case sheet with sign, date and time. The nurse should inquire about the patient's welfare from time to time after such treatment and make sure that everything has been running smoothly.

16.4.7 All adverse drug events must be filled by the concerned staff before the shift, in the prescribed ADR forms available in all clinical areas.

16.4.8 Labels, vials, packets of medicine due to which adverse event occurred shall be secured by on adverse events monitoring on duty staff nurse and given to committee.

16.4.9 All reports of ADRs collected should be given to the Deputy nursing superintendent through concerned Nursing sister in-charge, who will then give them to the DTC

16.4.10 The health facility may develop a ADR monitoring form or it may use the ADR monitoring form made by the Pharmacovigilance Program of India, Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India.

16.4.11 All adverse drug reactions/ events should be reported to the DTC in a standardized format. All adverse drug reactions are to be intensively analyzed by the DTC and corrective actions taken based on the discussion.

16.4.12 These events shall then be analyzed by the committee to identify probable cause and suggest and implement measures to prevent the same in future.

16.4.13 **Strategies to Avoid Errors Involving Medications:**

- Medication arrangement: Avoid storing look-alike, sound-alike drugs next to each other. Limit high risk drug storage.
- Formulary selection: Minimize look-alike, sound-alike formulary combinations.
- Prior verification: As an additional precaution, high risk medication orders are verified prior to dispensing.
- **High-risk medication**: To identify potential high risk medications and to outline steps to prevent errors that may result from confusion of these medications.
- Circumstances Increasing Errors in High Risk Medications: **Poorly** handwritten medication orders, Verbal directions/orders. Similar product packaging, Similar medication name, improper packaging leading to improper route of administration, storage of products with similar names in the same location, similar abbreviations, improper storage of concentrated electrolytes

16.5 Records

- Prescribed ADR forms duly filled
- Copy of the case sheets of patients reporting ADR
- Minutes of the meeting of the DTC on ADR.

16.6 Process Efficiency Indicators

- Reduction in the number of ADRs
- Awareness among health care providers about ADRs

16.7 Activities

- Regular review of the ADRs occurring by DTC

16.8 Reference

NABH: Pre Accreditation Entry Level Standards For Hospitals. April 2014

Pharmacovigilance Program of India

16.8 Definitions

Adverse Drug Reactions: Adverse drug reaction (ADR) is any noxious, unintended, undesirable, or unexpected response to a drug that occurs at doses used in humans for prophylaxis, diagnosis, therapy of disease, or for modification of psychological function.

Medication errors: A 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. Such events may be related to professional practice, procedures, and systems, including prescribing; communication; labeling, packaging, and nomenclature; dispensing; distribution; administration; education; monitoring and use.

Types of errors: Order Error – Types of ordering errors include: inappropriate medication selected, inappropriate dose, illegible order, duplicate order, order not dated/timed, wrong patient/chart selected, contraindications, verbal order misunderstood, verbal order not written in the drug chart, wrong frequency, route, illegible writing, therapy duration, alert information bypassed or use of nonstandard nomenclature or abbreviations.

Transcription error –Transcription involves orders that are manually transcribed (e.g. Drug chart). Types of transcription errors include : wrong medication, time, dose, frequency, duration,

rate, patient/chart, verbal order misunderstanding, verbal orders not entered into patient case sheet.

Preparation/Dispensing Error – Types of preparation and dispensing errors include: Inaccurate labeling, wrong quantity, medication, dose, diluents, formulation, expired medication, refill error, and delay in medication delivery.

Administration Error – Types of administration errors include: Wrong patient, dose, time, **m**edication, route, rate, extravasations (may be an ADR) and unauthorized dose given.

Form for Reporting Adverse Drug Reactions

Name of Patients

C R No

Age/ Sex

Unit - Bed No

Department

Reaction details

Action Taken

Outcome

Treatment history

S. No	Drug Name	Dose/ strength	Amount administered	Route	Action taken

Reporting Officers

Nursing sister on duty **Doctor on duty**

(Signature) **(Signature)**

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Department:	PHARMACY	SOP	17
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for procurement, storage and dispensing of narcotic and psychotropic drugs

17.1 Purpose

To provide guidelines governing adequate control for procurement, proper storage, dispensing and record keeping of Narcotic and Psychotropic Drugs in a Hospital.

17.2 Scope

All the important activities related to the procurement, storage, dispensing and record keeping of Narcotic and Psychotropic Drugs in accordance with the Delhi Narcotic Drug Rules, 1985 as well as Drugs and Cosmetics Act, 1940 and Rules framed there under.

17.3 Responsibility

- The Officer in-charge of MDS
- Pharmacist in-charge of MDS
- The Nursing Sister in-charge of respective departments of the hospital

17.4 Procedure

A separate license is required by the hospital for procurement, storage and distribution of Narcotic and Psychotropic Drugs from the local Excise Department.

17.4.1 The Narcotic and Psychotropic Drugs must be stored under lock and key in a separate cupboard.

17.4.2 Strict compliance of statutory requirements must be adhered to as provided under the Delhi Narcotic Drugs Rules, 1985, Delhi Narcotic Drugs (Amendment) Rules, 2002, Drugs & Cosmetics Act, 1940, Drugs & Cosmetics Rules, 1945 and Pharmacy Act, 1948.

17.4.3 Narcotic drugs and psychotropic substances must only be dispensed by a pharmacist against a proper prescription of a doctor authorized for the purpose. A facsimile of the prescription on Form-DD 12 required under Delhi Narcotic Drugs Rules, 1985 is at attached

17.4.4 Narcotic drugs and psychotropic substances must be procured and stored in such a manner so as to preclude their falling into the hands of unauthorized persons.

17.4.5 The storage area for the narcotic drugs and psychotropic substances may be opened and accessed by specific Pharmacist in-charge of MDS and Nursing Sister in-charge of respective department.

17.4.6 The cupboard or safe in which narcotic drugs and psychotropic substances are stored may be opened and accessed only when substances belonging to these categories are being placed into or taken out from the cupboard or room.

17.4.7 The area where narcotic drugs or psychotropic substances are stored shall be preferably equipped with a security alarm and/or surveillance system.

17.4.8 Narcotic drugs and psychotropic substances which are ready for dispensing to any one shall be stored in the place of storage until dispensation.

17.4.9 Pharmacist in-charge of MDS must check physically at least once every three months the stock of narcotic and psychotropic drugs stored. The same must be recorded in stock register and verified by the officer in-charge with signature and date.

17.4.10 The prescribing practitioner shall be responsible in case the prescription does not conform to statutory regulations. Nursing station shall ensure the entry of batch number in the prescription form while administering.

17.4.11 Appropriate registers shall be maintained to have information on usage. A proper record of their uses, administration and disposal shall be maintained at all the places wherever narcotic drugs are stored.

The narcotic drugs register must incorporate a record of all receipt and issue involving narcotic drugs. The narcotic drugs register must be a bound register with consecutively numbered pages. A separate page must be used for each narcotic drug.

17.4.12 Pharmacist shall be notified if any medicines or register is missing.

List of important Narcotic and Psychotropic Substances is at Annexure-2.

17.5 Records

- Separate stock register narcotic drugs in MDS,
- Stock register for narcotic drugs in Emergency
- Stock register for narcotic drugs in IPD
- Stock register for narcotic drugs in OPD

17.6 Process efficiency criteria

- The storage of Narcotic and Psychotropic Drugs be recorded and maintained as per statutory requirements.

17.7 Activity

- Audit by Officer in-charge MDS, Pharmacist in-charge and Unit in-charge, Nursing Sister in-charge, must be conducted at regular intervals, preferably on monthly basis.

17.8 References

- Drugs & Cosmetics Act, 1940.
- Drugs & Cosmetics Rules, 1945.
- Delhi Narcotic Drugs Rules, 1985,
- Delhi Narcotic Drugs (Amendment) Rules, 2002.
- The Pharmacy Act, 1948.
- NABH: Pre Accreditation Entry Level Standards For Hospitals. April 2014

17.9 Definitions

- **Narcotic Drugs** are the addictive drugs that reduce the user's perception of pain and induce euphoria (a feeling of exaggerated and unrealistic well-being). They are substances that lead to increasing tolerance and physiological dependence. They have a potential for abuse and/or addiction.
- **Psychotropic Drugs** – Any drug capable of affecting the mind, emotions, and behavior.

Forms for prescribing Narcotic and Psychotropic drugs

Form DD 12

[See Rule 15(1)]

OFFICIAL FORM OF PRESCRIPTION to be used when preparations containing manufactured drug are prescribed

Not to be repeated.

(To be repeated at the interval of _____ days)

(Note:- Cross out one of the two alternatives)

1. Name, address and description of the person to whom the prescription is issued:
2. Nature of the ailment:
3. Directions for use:
4. Dose (if in excess of usual doses):
5. Amount of drug to be supplied at one time:
6. No. of Registration certificate in Form D.D. 8 or D.D. 5 License of approved Practitioner:

Address:

Date:

…….

…….

Full name, qualification and signature of the Approved Practitioner

1. Name of the Licensed Chemist who dispenses the prescription.
2. Address of premises.
3. Date.

CONDITIONS

(a) The prescription can be prescribed only by those approved Practitioners who are either registered with Collector of Excise on this behalf and have obtained Registration Certificate in form DD-8 or holding a License in Form DD-5.
(b) On the authority of this prescription, the drug must not be supplied to the holder more than 6 times.
(c) The prescription shall not be given for the use of prescriber himself.
(d) A registered dentist shall give a prescription only for the purpose of dental treatment and shall make if 'for local dental treatment only'.
(e) A registered veterinary surgeon shall give prescription only for the purpose of treatment of animals and shall make it for local dental treatment only.
(f) An approved Practitioner of Indigenous system of medicine may prescribe only those drugs which are included in the indigenous system of medicine.

List of commonly prescribed narcotic and psychotropic drugs

NARCOTIC DRUGS

Morphine and its preparations

Pethidine and its preparations

Codeine and its preparations

Opium and its preparations

PSYCHOTROPIC SUBSTANCES

Amphetamine / Dexamphetamine

Methaqualone

Pentazocine

Alprazolam, Ketazolam, Lorazepam

Diazepam, Nitrazepam, Oxazepam

Meprobamate

Barbiturates

Buprenorphine

Dextropropoxyphene

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Department:	PHARMACY	SOP	18
Division:	Store, Sub Store, IPD, OPD	Implementation Date:	
Prepared by:		Review Date:	
		Approved By:	

Procedure for periodic random check and quality testing of drugs

18.1 Purpose

To establish a procedure with a view to ensure that only quality drugs are available to the patients.

18.2 Scope

All activities for ensuring that only drugs of standard quality, efficacy and safety are available for the patients.

18.3 Responsibility

- The Pharmacist in-charge of MDS.
- Officer in-charge of MDS.

18.4 Procedure

18.4.1 At the time of receiving the drugs Pharmacist in-charge MDS must verify the quantity, physical appearance, batch number expiry date and proper label.

18.4.2 Officer in-charge of MDS will do random checking of drugs received.

18.4.3 The items received in the MDS of a hospital must be randomly checked for physical appearance. Samples for laboratory testing may be picked by an Officer appointed by Head of the Institution.

18.4.4 In case of any doubtful quality of the drug received or found stored, the entire quantity of the particular batch should be quarantined in a separate area away from other

stock & the same must be documented in a separate register This batch of stock should not be used till the standard quality report is not received.

18.4.5 In case of any doubtful quality of the drug in the Departmental sub-store, it will be the responsibility of Nursing Sister in-charge to quarantine the drug, inform the Doctor in-charge of the Unit and the same should be sent to MDS for necessary action. Officer in-charge of MDS shall send the same drugs for laboratory testing preferably from NABL accredited laboratory, preferably empaneled by Government. The testing expenses will be borne by the hospital concerned. Alternatively Drugs Control Department, Delhi may be requested to get the sample of the particular drug collected from the hospital and get it analyzed from the Government Laboratory and submit report.

18.4.6 In case the sample is reported to be of "Not of Standard Quality " (NSQ) the stock must not be consumed and efforts must be made immediately to get the entire batch replaced with fresh stocks accompanied with standard quality report in respect of the particular batch from the supplier. CPA/ DHCL must be informed about the " Not of Standard Quality" (NSQ) report for necessary action against the manufacturer/supplier for any punitive action.

18.4.7 In case the sample is reported to be of Standard Quality the stock can be released for distribution and consumption in the hospital.

18.5 Process Efficiency Criteria

- Drugs received in the hospital must meet with the requirements laid down under the Drugs and Cosmetics Act, 1940 and the Rules (1945) framed there under.

18.6 Activity

- Regular random checking of quality of drug stored in the MDS, sub-store, Pharmacy (OPD) and wards in the hospital must be conducted by Officer in-charge MDS, Pharmacist in-charge and the Nursing Staff.

18.7 References

- Drugs & Cosmetics Act, 1940.
- Drugs & Cosmetics Rules, 1945.

18.8 Definitions

- Quality Control means and includes checking and directing the degree or grade of excellence of processes and products. Quality control ensures that drugs of prescribed quality, efficacy and safety are produced by the manufacturer and on being stored properly throughout their journey till they reach the end user, retain their efficacy. This process provides assurance to the physician, the pharmacist and the consumer that the given drug performs uniformly and in a satisfactory manner for the purpose it is intended.

- Random Check means and includes inspecting and keenly observing anything to see and find out if the same meets with established standards for the said item/drug.

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दिल्ली सरकार

आप की सरकार

Department of Health & Family Welfare, GNCTD