DRAFT GUIDELINES ON STANDARDS FOR ESTABLISHMENT OF HOSPITAL PHARMACIES IN PAKISTAN

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Drug Regulatory Authority of Pakistan
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Table of Contents

1. HISTORY

This is the first edition of this document.

2. APPLICATION - Guidance Document

This document is for the guidance and support of pharmacy or pharmacy services department within a hospital to develop and maintain the required minimum standards. It applies to following pharmacy establishments:

i. All hospital pharmacies (as per respective scope of work) in public and private sector.
ii. All pharmacists who are involved in delivering pharmacy services within the scope of the hospital and its pharmacies.

3. PURPOSE

These standards outline the level of services that are expected from hospital pharmacies in a consistent manner. Certain elements of these standards will be useful in evaluating the scope and quality of Pharmacy Services.

The purpose of these guidelines is to provide guidance and standards for:

i. Organization, management and facilities of a hospital pharmacy, relevant HR, committees, required policies, job description etc.
ii. Hospital in the procedure of medicine procurement, storage, inventory, procedures from its preparation to administration and monitoring of use thereafter.
iii. Evaluating the effectiveness of medicine use, identification of weaknesses and improvement of the system.
iv. HR development and training.

4. INTRODUCTION

The following standard guidelines are intended to serve as a basic guide for the provision of pharmacy services in the hospitals within the country. These guidelines outline a set of services that are expected from hospital pharmacy departments.

Terminology The term "shall" is used to indicate a minimum standard of practice set forth in requirements established by laws and regulatory, authorities. The term "may" is used to indicate a best practice that is strongly encouraged by regulations and authorities but which may not be applicable to all institutions or in all circumstances.

5. DEFINITION AND ACRONYMS:

AC	Air conditioner
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
CPR	Cardiopulmonary Resuscitation
D&TC	Drug and Therapeutics Committee
DRAP	Drug Regulatory Authority of Pakistan
HAMs	High Alert Medications
HMIS	Health Management Information System
ISO	International Organization for Standardization
IV	Intravenous
JCIA	Joint Commission International Accreditation
JD	Job Description
LASARA	Look-Alike, Sound-Alike and Read-Alike
P&TC	Pharmacy & Therapeutics Committee
SOP	Standard Operating Procedure

Cardiopulmonary Resuscitation	An emergency lifesaving procedure performed when the heart stops beating.
Competence (or competency)	The set of demonstrable characteristics and skills that enable and improve the efficiency or performance of a job.
High Alert Medication	Drugs/medicine that bear a heightened risk of causing significant patient harm when they are used in error.
IV Admixture	A resulting combination when one or more sterile products are added to a 50 mL or larger bag or bottle of IV fluid for parenteral administration.
Look Alike Sound Alike (LASA) medications	Involve medications that are visually similar in physical appearance or packaging and names of medications that have spelling similarities and/or similar phonetics.
Mission & Vision Statement	A Mission Statement defines the organization's business, its objectives and its approach to reach those objectives. A Vision Statement describes the desired future position of the company. Elements of Mission and Vision Statements are often combined to provide a statement of the company's purposes, goals and values. However, sometimes the two terms are used interchangeably.
Near Miss	An act of commission or omission that could have harmed the patient but did not cause harm as a result of chance, prevention, or mitigation
Performance Evaluation	A formal and productive procedure to measure an employee's work and results based on their job responsibilities.
Pharmacist	A person who is registered under section 24 in register A and register B of Pharmacy Act 1967 as amended up to 8th Feb 1973.
Pharmacy Services	Services rendered by a Pharmacist in a pharmaceutical care, selection, posology, counseling, dispensing, use, administration, prescription, monitoring, pharmacoepidemiology, therapeutic goods information and poison control, pharmacovigilance, pharmacoeconomics, storage, sales, procurement, forecasting, supply chain management, distribution, drug utilization evaluation, drug utilization review, formulary based drug utilization and managing therapeutic goods at all levels including pharmacy, clinic, medical store, hospital or medical institution.
Policy and Procedure	A set of rules and methods designed and communicated to structure certain processes within an organization.
Standard Operating Procedure	A set of step-by-step instructions compiled by an organization to help workers carry out routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply.

6. STANDARD-I ORGANIZATION AND MANAGEMENT

6.1. Medication use in the hospital shall be organized to meet patient needs and requirements, complies with applicable laws and regulations, and shall be under the direction and supervision of a skilled pharmacist who has completed training in hospital pharmacy and/or has relevant experience in the field. Medicines management covers a number of tasks including prescribing/ordering, dispensing, receiving/ transporting, storing, assessing, preparing, assisting, administering, disposing and verifying dispensed medicines. It also includes medicines reconciliation.

6.2. Applicable laws and regulations (Federal, Provincial and other local laws etc) related to Pharmacy Services and medication use in hospitals shall be met and relevant documentation of compliance shall be maintained. These include Drug Act,1976 and rules framed thereunder, Drug Regulatory Authority of Pakistan Act, 2012 and rules framed thereunder like Pharmacovigilance Rules, 2022, The Alternative Medicines and Health Products Enlistment Rules, 2014, Medical Device Rules, 2017, Ethical Marketing to Healthcare Professional Rules, 2021, Pharmacy Act, 1967, relevant Healthcare Commission, and/or Health Regulatory Authorities Standards.

6.3. The Head of Pharmacy Services (titles may vary as Chief of Pharmacy, Director, or Manager Pharmacy etc.) shall be responsible and accountable for professional coordination, selection and use of therapeutic goods (as defined in DRAP Act, 2012). A sample job description is available (Annexure-III).

6.4. The hospital shall have 1 (one) Pharmacist for every 50 beds at In-patient area, however, out-patient staffing depends upon the volumes and pharmacy stations. Pharmacist staffing provision for clinical pharmacy services and specialized activities should also be considered.

Placement of Clinical pharmacists (as notified by Federal/Provincial govt.) if the hospital's bed size is >50, and/or dealing with high-risk services such as Oncology, Transplant, Infectious diseases, Critical Care, Pediatrics, Neonatology etc. or if High alert medicines (as notified by the DRAP) are routinely used in the hospital.

6.5. The pharmacy shall have a written mission & vision statement and a written document describing the scope of pharmacy services. The mission statement and scope of services should be consistent with the hospital's mission and reflect both patient care and

operational responsibilities.

6.6. The mission and scope of pharmacy services shall be clearly communicated to everyone involved in the provision of pharmacy services including pharmacists, technicians, and support staff.

6.7. The scope of service document should minimally contain the following:

- 6.7.1. Type, nature, and extent of available pharmacy service.
- 6.7.2. Specialty areas and type of patients catered by pharmacy.
- 6.7.3. Working hours of pharmacy.
- 6.7.4. Arrangement of medication supply during off-hours.
- 6.7.5. Staffing plan (duties management).
- 6.7.6. Emergency/backup plan in case of inadequate staff.

6.8. There shall be a policy and procedures governing pharmacy functions (e.g., administrative, operational, and clinical role of pharmacy services and all pharmacy personnel shall follow those policies and procedures. Healthcare Organization has its own policy and procedure depending upon their size, structure and clinical function and each private/public hospital will develop its policy keeping in view structure/scope. However, the same policy can be developed by concerned provincial government for all the public hospitals to work uniformly. List of key pharmacy's operational, administrative, clinical policy titles in the annexure for easy reference (Annexure-IV).

6.9. The policy and procedure shall be reviewed and approved by the head of pharmacy along with a designated medical staff committee e.g., Pharmacy & Therapeutics Committee/Drug & Therapeutics Committee (P&TC/D&TC) (where indicated), for the safe & effective medication use involve a multidisciplinary, coordinated effort of health care practitioners applying the principles of process design, implementation, and improvement to all aspects of the medication management process, which includes the selecting, procuring, storing, ordering/prescribing, transcribing, distributing, preparing, dispensing, administering, documenting, monitoring of medication therapies, any potential conflicts related to medication and resolution regularly. Policies and procedures are revised as necessary to reflect changes in procedures, organization, objectives, or practices as per definition of Pharmacy Services as per DRAP Act, 2012.

6.10. The pharmacy policy and procedures shall be accessible and be communicated to pharmacy department personnel as well as other healthcare staff of the hospital.

6.11. Appropriate mechanisms to ensure compliance with the policies and procedures should be established. Internal audit mechanism and quality management standards against

set procedure is an appropriate mechanism to ensure compliance.

6.12. Adequate hours of operation for the provision of necessary and emergency pharmacy services shall be maintained with 24-hour pharmacy services, wherever required like hospitals that require intensive medication therapy management (e.g., critical care units, oncology service, transplant programs, critical/complex surgeries, neonatal/pediatric intensive care units, and 24hrs emergency/ trauma centers, etc.).

6.13. When 24-hour pharmacy services are not feasible, a designated pharmacist shall be available on an on-call basis (contact information communicated to the key aforementioned essential medical units).

6.15. In the absence of 24-hour pharmacy services, access to a limited supply of medications shall only be available to authorized, licensed healthcare professionals (e.g. Registered Nurse) in carrying out urgent medication orders.

6.16. After-hours access and storage of medications shall be carefully managed and documented by the pharmacy on regular basis to ensure appropriate use.

6.17. All medications stored outside of the pharmacy shall be protected from loss and theft and shall be stored under optimum storage conditions (as per the manufacturer recommended temperature and humidity limits) under authorized access.

6.18. Routine after-hours access to the pharmacy by non-pharmacists for access to medications is not recommended. (As per the hospital's own policy).

6.19. The pharmacy shall establish, in conjunction with the hospital-wide emergency plan, policies and procedures for the safe and orderly evacuation of pharmacy personnel in the event of an emergency in the hospital (Annexure-IV).

6.20. The pharmacy shall participate in hospital decisions about the contents of crash cart trolleys, emergency medication supplies; kits and trays, floor stock inspection and the role of pharmacists in medical emergencies.

6.21. Each pharmacy shall have contingency plans for medicine shortages and emergencies (e.g. natural or man-made disaster).

6.22. The pharmacy shall participate in the development of hospital policies and procedures concerning preventive and post-exposure immunization programs for patients and hospital employees in line with the infection control / hospital policies.

6.22.1 The pharmacy shall participate in the development and implementation of hospital policies and procedures concerning medications such

as: process and formats for medication prescription/orders, taking medication history medication administration record, and orders at admission and discharge, signing offs or handover between shifts (or at the transitions of care).

6.22.2 Medication use protocols/guidelines.

6.22.3 Patient assessment parameters required to correctly order (by physician), dispense (by Pharmacist) or administer (by Nurse) a medicine (such as patient demographics, diagnostic tests (e.g. serum creatinine, electrolytes, blood cultures, diagnosis, allergies, etc.).

6.22.4 Restricted Prescribing.

6.22.5 Medication reconciliation process.

7. STANDARD-II FACILITIES

7.1. Adequate infrastructure, space, equipment, lighting, ventilation, and supplies shall be available for all professional and administrative functions relating to pharmacy services in line with the prevailing applicable laws/regulations/guidelines.

7.2. There shall be suitable facilities and equipment to enable the receipt, storage and preparation of medications under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, dispensing and security to ensure medication integrity and personnel safety throughout the hospital. Each hospital has its own procurement process and medicine list as per the need and scope of services.

7.3. Biologicals / medicine and vaccine refrigerators may be available in the hospital pharmacy. Thermolabile products require refrigeration and stored in pharmacy specific refrigerators (that maintain 2-8 °C).

7.4. Pharmacy temperature and humidity controls shall be independent of the rest of the hospital so that uninterrupted, uniform conditions are maintained for medication storage areas. Changes in the hospital environment shall not affect the pharmacy and rest of the medication storage areas' temperature and humidity controls e.g., when AC is shut down in off-hours in some parts of the hospital or when heating is turned on in winters for patient care areas.

7.4.1 Ambient/Room Temperature for medicines storage: 20-25°C

7.4.2 Humidity limit for medicine storage: < 60 %

7.5. Medicines requiring light protection:

7.5.1 These should be placed in their original cartons, or opaque bins/ boxes/containers when stored in the shelf.

7.5.2 At the time of dispensing, amber-colored containers, plastic bags or overwraps can be used.

7.5.3 During administration where indicated, such as for prolonged infusions, the IV bags can be covered with amber-colored overwraps, while the syringe and the tubings can be covered with aluminum foil or suitable alternate(s).

7.6. There shall be suitable facilities to enable the compounding, preparation, and labeling of sterile and non-sterile products as per applicable standards. Equipment and facilities should ensure that medicines are prepared correctly, with the required level of sterility and quality.

7.7. Hazardous drug products are prepared in the designated areas such as chemotherapy admixture service with necessary equipment and facilities according to applicable standards. Equipment and facilities should ensure that hazardous medicines are prepared correctly, with the required level of sterility and quality, and exposure to staff and patients/visitors is prevented.

7.8. Compounding and IV admixture facilities shall be segregated from routine dispensing and medicines storage areas.

7.9. Pharmacy equipment (e.g. clean bench, electronic tablet counters, temperature and humidity monitoring devices, label printers, computers etc.) shall be adequately maintained and certified (validated and calibrated) in accordance with applicable standards, laws, and regulations. There shall be documentation of periodic (annual and biannual, depending upon equipment) maintenance and certification of equipment. The maintenance and calibration/validation of equipment is usually done by the facility management division of the hospital or is outsourced to 3rd party and this should be included in the internal audit check list in order to ensure compliance.

7.10. In outpatient pharmacy settings, a private area for pharmacist-patient consultations should be designated to provide detailed medicine education and counseling to patients in a confidential manner. Patient education material can also be prepared and displayed for quick reference and guidance.

7.11. A comprehensive pharmacy computer system like shall be employed (where

feasible for public sector hospitals) and may be fully integrated with other hospital management information systems and software, including computerized provider order entry, medication administration, electronic health records, patient billing systems, etc.

7.12. Electronic systems such as Health Management Information System (HMIS) would be beneficial for improvement in the health system and centralization of the system would add to development of health databases (such as patient information database with medication and medical history) this would aid in developing and improvement in pharmacovigilance systems.

7.13. In hospitals, where HMIS have not been implemented, pharmacists' access to the required/necessary information (such as patient records, history, progress notes, diagnostics, etc.), proper manual integration of medication ordering with dispensing, administration record, and ultimately to the billing system shall be ensured.

7.14. Up-to-date, prompt, drug information resources (e.g. books, online information access, software for drug information etc.) shall be available to healthcare professionals, who prescribe, dispense, prepare, and administer medicines like access to Drug & Poison Information centers (operating within the hospital or country), current print or electronic periodicals, newsletters, drug information software, best-practices guidelines, and recent editions of reference books, etc.

7.15. All records shall be maintained in accordance with applicable laws, regulations, and institutional policies/guidelines.

7.16. Appropriate licenses and permits shall be on display or kept in file as required by law / regulation/guidelines.

8. STANDARD-III SELECTION AND PROCUREMENT

8.1. The Pharmacy (or Drug) and Therapeutic Committee (P&TC/D&TC) and Medical/Surgical Purchase Committee shall be established and organized in the hospitals and a pharmacist shall be appointed as the secretary of the committee.

8.2. P&TC/D&TC shall have representation of physicians from key clinical specialties, hospital leadership along with nurses, material management representation and pharmacists as core members of the committee (Annexure-2).

8.3. The P&TC/D&TC organization and authority may be outlined in the organization's medical staff by laws or medical staff rules and regulations, and other organizational policies, as appropriate.

8.4. A well-controlled hospital formulary of approved medications shall be maintained and regularly updated by the P&TC/D&TC committee.

8.5. The P&TC/D&TC shall be responsible for developing and maintaining written criteria for drug product selection, which shall address formulary requests for medications intended for use in special populations (e.g., pediatric or geriatric populations), and also for deletion of drug products from the formulary (Annexure-2).

8.6. The P&TC/D&TC shall be responsible for developing and maintaining adequate product specifications to aid in the:

8.6.1 Hospital medication/surgical tender process (where applicable).

8.6.2 Purchase of medications and related supplies.

8.6.3 Safe, effective, and rational use of medications and related supplies.

8.7. The pharmacy shall disseminate the formulary by electronic (preferred) or other means to meet the needs of all health care professionals.

8.8. There shall be policies and procedures that address the use of special medicinal products e.g. dietary supplements, radiopharmaceuticals, surgical devices, implants, and other alternative therapies etc.

8.9. There shall be policies and procedures for the procurement, control, and use of non-formulary medications, sample drugs, study/trial drugs and medicines that are brought in by patients, etc.

8.10. The pharmacy shall be responsible for the procurement, distribution, and control

of all drug products used in the hospital for inpatient and ambulatory patients. Policies and procedures governing these functions shall be developed by the pharmacy with input from other appropriate hospital healthcare staff and committees. In case the pharmacy is not directly involved in procurement, the concerned department shall carry out purchases as per standard protocol in compliance with applicable laws and regulations. The pharmacy shall provide technical and professional inputs in the purchase process wherever indicated and required.

8.11. Criteria for selecting drug product manufacturers and suppliers shall be established by the pharmacy (in coordination with the purchase team) based on technical evaluation to ensure the quality and the best price for drug products.

8.12. There shall be policies and procedures for managing medication acquisition. These policies and procedures should address such issues as formulary development (including initial evaluation for formulary consideration, prescribing restrictions, medication- utilization review programs, therapeutic interchange, etc.), competitive bidding, bulk purchasing, medication shortages, outsourcing, and cost-effective patient services.

8.13. Once products are selected there shall be an ongoing mechanism to assess the quality and safety of the approved products. Methods may include but are not limited to are: Post addition use evaluation, feedback from key users/prescribers, review of recalls, incidents, Adverse Drug Reactions (ADRs), or Adverse Drug Events (ADEs) related to these products, testing by relevant laboratory etc.

9. STANDARD-IV STORAGE AND INVENTORY MANAGEMENT

9.1. Medications shall be received, stored, and prepared under proper conditions of temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety.

9.2. When medications are stored in individual patient care units, ambulances, or other areas outside of the pharmacy, the organization should perform a risk assessment to identify the conditions suitable to maintain product stability for the length of time the medications are stored outside of the pharmacy, as applicable.

9.3. Storage of medications in non-pharmacy areas (e.g., patient care and procedural areas) shall, to the extent possible, be limited to medications for emergency use and routinely used personal care items (e.g., mouthwash and antiseptic solutions).

9.4. A separate assessment may occur for every location where medication may be stocked.

9.5. All stocks of medications (within or outside the pharmacy) shall be inspected routinely to ensure the integrity of the product, security, absence of expired, unusable, recalled, or mislabeled products.

9.6. Controlled substances (Narcotic Drugs, Psychotropic Substances and Precursor Chemicals) are accurately accounted for according to applicable laws/regulations/ guidelines.

9.7. Medications or products requiring special handlings, such as radioactive medications, investigational medications, and other similar medications or products, shall be accurately labeled and safely stored (segregated facility), administered, and monitored.

9.8. Medications and chemicals used to compound medications shall be accurately labeled with contents, expiration dates, and warnings.

9.9. Medications must be protected from loss or theft throughout the hospital.

9.10. High alert medicines are stored, handled, and used in accordance with DRAP's Guidelines on High Alert Medication Management.

9.11. Concentrated electrolyte products (such as potassium chloride (undiluted), hypertonic saline (equals to and greater than 2% saline), and magnesium sulphate) and high alert medicines shall be stored in a secure, segregated place with distinct labels.

9.12. The medication samples may be used as per policies and procedures to ensure their

safe use.

9.13. Drug products and related devices brought into the hospital by patients are required to be identified by the pharmacy and if possible documented in the patient's medical record if the medications are to be used during hospitalization.

9.14. Traceability of medications from receiving in the facility till the administration may be available for ensuring effective recall and incident management. The use of technology like barcodes may be explored by healthcare organizations.

9.15. There shall be a written policy and procedure for:

9.15.1 The timely handling and documentation of a drug product recall on the directions of DRAP or information by the registration holder. These procedures should include an established process for immediate removal of any drugs or devices subjected to a recall, notifying appropriate health care professionals, identifying patients who may have been exposed to the recalled medication, and, if necessary, communicating available alternative therapies to prescribers.

9.15.2 Use and disposition of expired or known to be expired products.

Disposition of defected products.

9.15.3 Managing drug product shortages. The pharmacy's inventory management system should be designed to detect subminimum inventory levels and alert the pharmacy to potential shortages, and pharmacy staff should monitor reliable sources of information regarding drug product shortages.

9.15.4 Mock Recall activity may be performed annually for emergency preparedness and SOP may be prepared for this purpose.

10. STANDARD-V PREPARATION, LABELLING AND DISPENSING

10.1 Preparation involves:

10.1.1 Preparing/admixing the injectable medicine in its diluent, and dispensing it in a suitable administration modality e.g. syringe, IV fluid (drip), piggyback (small volume parenteral of 50-100ml etc.), elastomeric infusion pumps etc.

10.1.2 Compounding syrups, solutions, ointments, cream, enemas, capsules, eye drops, irrigation solution or other dosage forms for patient specific use.

10.1.3 Reconstitution of powder dosage forms.

10.1.4 Admixing 2 or more ingredients in a diluent to form a 'composition' for parenteral use (e.g. electrolytes like Potassium Chloride and Magnesium Sulfate mixed with diluent like Normal Saline).

10.1.5 Admixing ingredients along with dextrose, amino acid and/or lipid to make "parenteral nutrition".

10.1.6 Repackaging the bulk form into smaller unit dose products, or drawing up the dose in suitable container to cater for a patient specific dose (e.g. prefilling syringes or drawing up a 50mg of medicine dose from its 500mg vial).

10.2 Labelling includes:

10.2.1 Labelling a product with 'pharmacy label' to depict patient identification (Name, MR# and bed/ward), product identification (brand, generic name, strength, dosage form), dose, route of administration, quantity dispensed, date, time of dispensing.

10.2.2 Medication labels may be clear and have sufficient information to ensure safe administration, including at least 2 patient identifiers (for example patient name and medical record but not patient room), the name of the medicine, prescribed route, dose, and, where appropriate, volume and rate of administration.

10.2.3 Pasting auxiliary labels on medicine to highlight the precautions associated with that particular medicine. e.g. "do not crush", "not for injection use", "not for oral use", "High Alert Medicine", or "look-alike / sound-alike / read-alike (LASARA) medicine" etc.

10.2.4 Labelling a prepared medicine (see part 1 above) with its date of preparation, date/time of expiry and storage/use instructions (e.g. Refrigerate or protect from light or shake well before use etc.).

10.2.5 Clinicians and pharmacists, in collaboration with medical and nursing staff, shall develop policies and procedures based on demonstrated best practices for ensuring the optimization of medication therapy.

10.2.6 All prescriptions shall be reviewed, interpreted, and validated by a hospital/clinical pharmacist before dispensing and administration of medicines.

10.2.7 Pharmacists shall review all orders for appropriateness (i.e. selection of drug as per indication, dose, route, frequency, duration, duplication, interactions, potential allergies, contraindications, etc.). If problems are identified, pharmacists shall communicate with the prescriber to resolve the issue and then dispense the medicine.

10.2.8 At an advanced level, pharmacists are also engaged in medication therapy management, or collaborative drug therapy management, the development of pharmaceutical care plans, immunization, and administration, and other patient care activities to the extent permitted by law, regulation, and hospital requirements.

10.2.9 Drug formulations, dosage forms, strengths, and packaging that are not available commercially but are needed for patient care shall be prepared/compounded by appropriately trained pharmacy personnel in accordance with applicable practice, standards and regulations.

10.2.10 Written master formulas and batch records (including product test results, as appropriate) shall be maintained, and a lot number or other method to identify each finished product with its production and control history shall be assigned to each batch.

10.2.11 All sterile medications shall be prepared and labelled in a suitable environment by appropriately trained personnel in accordance with established quality standards such as United States Pharmacopoeia (chapter 797: “Pharmaceutical Compounding--sterile preparation”).

10.2.12 Sterile compounding outside the pharmacy or satellite pharmacies (e.g., by nursing staff on nursing units) may be minimized and occur only in emergency situations. A summarized chart displaying common diluents and rate of infusion may be displayed at nursing station and updated regularly to avoid errors.

10.2.13 There shall be policies and procedures that describe special precautions, equipment, and training for the preparation, handling, storage, and disposal of hazardous drug products and products used in their preparation including cytotoxic medicines.

10.2.14 Hospital pharmacists should ensure that medicines are packed and appropriately labelled (drug product details and patient identification) and to maintain integrity before administration to the individual patient.

10.2.15 Whenever possible, medications may be available for inpatient use in single-unit packages and a ready-to-administer dosage form possible. Manipulation of medications before administration (e.g., withdrawal of doses from containers, reconstitution of powdered drug products, labelling of containers, and splitting of tablets) by final users should be discouraged.

11. STANDARD-VI MEDICATION ADMINISTRATION

11.1. Only personnel who are authorized by the hospital in accordance with applicable laws and regulations and appropriately trained shall be permitted to administer medications to a patient.

11.2. Medication administration timings are standardized across the hospital and dispensing of due doses is according to standard administration timings.

11.3. All administered, refused, or omitted medication doses should be recorded in the patient's medical record according to an established procedure, and all medications that have not been administered should be returned to the pharmacy.

11.4. No medication may be administered to a patient unless medical and nursing personnel have been provided with adequate information about, and are familiar with, its therapeutic use, method of administration, potential adverse effects, and dosage. Test dose shall be administered as required.

11.5. No medication shall be administered without a doctor's prescription.

11.6. Unused intact medicines shall be promptly removed from patient care areas and returned to the pharmacy (or floor stock).

11.7. Leftover medicines shall be discarded promptly as per the defined policy and procedure of the hospital.

11.8. Doses of chemotherapy and other high alert medicines should be independently checked against the original prescription by at least two healthcare professionals, before administration.

11.9. At the time of discharge, patient shall be educated and counselled for the discharged medications.

12. STANDARD-VII MONITORING OF MEDICINE USE

12.1. An easily accessible reporting system for defective medicines, adverse drug reactions (ADRs), medication errors, and near-misses shall be established and maintained in the hospital. Reports of ADRs/medical errors/near misses and quality defects shall be reviewed internally by the pharmacy and relevant committee (e.g. P&TC) or pharmacovigilance committee on a regular basis. Thereafter, all reports of ADRs and quality defects and those reports of medical errors which are associated with adverse outcomes shall be reported to the provincial or regional pharmacovigilance centre as per National PV Guidelines 2022 and Pharmacovigilance Rules, 2022. Other data on medication errors/near misses should also be regularly reviewed to improve the quality and safety of medicine use practices at the institutional level and only share the outcome with the Provincial and National Centre to acknowledge and improve the healthcare delivery.

12.2. The medicines use process may be reviewed through an external accreditation or quality improvement programs, where applicable (e.g. Healthcare Commission, Regulatory Authorities, etc.). Hospitals should act on reports learn from incidents and preventable events with risk minimization measures and education/learning measures to improve the quality and safety of their practices.

12.3. Pharmacists' clinically relevant activities (like drug utilization evaluation, drug utilization review etc) may be documented, collated and analyzed to improve the quality and safety of medicine use and patient outcomes. Activities that significantly impact individual patient care should be documented in the patient record.

13. STANDARD-VIII EVALUATING THE EFFECTIVENESS OF THE MEDICIATION USE SYSTEM

13.1. The pharmacy shall have an ongoing, systematic program for periodic quality assessment and improvement of pharmacy services and the medication-use system.

13.2. The pharmacy shall develop and monitor the departmental key performance indicators (KPI) to ensure the ongoing provision of services at a satisfactory level. Examples of pharmacy KPIs may include:

13.2.1 Number (or %) of dispensing errors.

13.2.2 Timely dispensing (dispensing turnaround time).

13.2.3 Number (or %) of pharmacists' interventions documented.

13.2.4 Percent value of expired/wasted inventory or inventory variations (shortage/excess).

13.2.5 % of patients educated/counselled, patient medication profiles reviewed, medication reconciliations performed, etc.

13.3. The pharmacy shall have an ongoing process for consistent documentation of the patient care services provided by pharmacists.

13.4. There shall be an ongoing program for monitoring drug utilization and costs to ensure that medications are used appropriately, safely and effectively and to increase the probability of desired patient outcomes.

13.5. There shall be an ongoing program for antimicrobial stewardship and infection prevention and control including at least one pharmacist as a member for active participation to promote the optimal use of antimicrobial agents, reduce the transmission of infections, and educate healthcare professionals, patients and public about the topics.

14. STANDARD-IX HUMAN RESOURCES, TRAINING AND DEVELOPMENT

14.1. Hospital pharmacy workforce plans may describe strategies for human resource education and training, recruitment and retention, competency development, remuneration, and career progression pathways, diversity-sensitive policies, equitable deployment and distribution, and roles and responsibilities of stakeholders for implementation.

14.2. All new pharmacy staff shall receive adequate orientation and training before work is assigned. All training and education record should be documented.

14.3. All pharmacy staff shall be educated about the basics of medication management and use standards, high alert medicines, applicable organizational policies and procedure, and laws and regulations.

14.4. All pharmacy staff shall be provided with written job descriptions.

14.5. All pharmacy staff shall receive ongoing in-service training, capacity building, and continuous professional development as identified, managed, or arranged by the

pharmacy department.

14.6. There shall be a mechanism for baseline and periodic competency assessment of pharmacy staff.

14.7. The appraisal/performance evaluation of pharmacy staff is carried out and documented at a regular interval. The same may be used as a source for future training recommendations.

14.8. Pharmacists shall maintain the registration of their respective pharmacy council updated and keep the registration current and valid.

14.9. The pharmacist shall maintain the validity of their clinical/pharmacy practice-related professional certification current and valid at all times.

14.10. Procedures can be put in place for encouraging better performance. Pharmacy staff with consistent breach of standards/policies, and reckless or at-risk behavior shall be dealt with as per hospital or government policy *invogue*.

14.11. Pharmacy staff with consistently good performance, exemplary conduct, and professionalism shall be formally appreciated as per prevailing hospital/government policy.

14.12. Pharmacy staff shall be actively engaged in a review of the trends of the department's KPIs, discussion on the challenges, their opinion in resolving issues are sought and their role is integrated with the hospital's mission and vision.

14.3. The training programs of pharmacy support staff should be formalized.

14.4. Hospital pharmacists may provide orientation, drug information, and education to nurses, physicians, and other hospital staff regarding best practices for medicine use and maintain all record. This education or these sessions can be planned on the basis of weak areas of medication use system through evaluation of performance and identification of errors and events. These can also be planned on the basis of any new research, emergency issues and current global challenges regarding patient safety.

14.5. Hospital pharmacists may actively engage in research into new methods and systems to improve the use of medicines and human resource needs in hospital pharmacies.

14.6. Pharmacist may be trained and maintained the certificate for BLS (Basic Life Supports

15. REFERENCES:

1. ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals
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16. ACKNOWLEDGEMENT:

Pharmacy Services Division, DRAP acknowledges the contribution Ms.Aasma Hamid (Director Pharmacy, Dow University of Health Sciences Karachi) and Ms.Qurat ul Ain Tausif (Deputy Manager Quality Assurance, Department of Pharmacy, Liaquat National Hospital Karachi) Members PSHP for their contribution in the development of these guidelines.

Annexure-I

Hospital Pharmacy Standards Assessment Checklist

S#	Assessment Points	Yes	No	Comment
1.	a. Pharmacy has a valid and relevant drug sale license (DSL) (e.g. compounding, narcotic etc.) b. Head of Pharmacy Services is a qualified pharmacist (Category A). c. Pharmacists and Technicians are the fulltime employee of the hospital. d. All pharmacists have their valid/renewed Pharmacy council registration (license). e. Attendance record of qualified person is maintained regularly. f. All staff are provided with their current job descriptions (JDs).			
2.	a. Scope of Pharmacy Services is defined and written down as per Policy. b. Scope of pharmacy services is periodically revised as per defined frequency. c. Pharmacy/hospital maintains a policy and procedure manual pertaining to key operations and procedures of the pharmacy services. d. Pharmacy/hospital maintains a policy and procedure manual pertaining to the medication use processes and systems across the hospital. e. Staff safety plan is developed for pharmacy service (e.g. related to man-made or natural disasters, chemicals and hazardous drugs etc.) f. A contingency plan is available for smooth medication supplies during disasters and/or during critical medicine shortages. g. Only authorized medicines and supplies are stocked and dispensed.			
3.	a. Pharmacy has adequate infrastructure (as per harmonized standards preferably in accordance to FIP/ASHP guidelines) to meet legal and operational requirements for the safe and accurate medicine storage, order review, preparation and dispensing, safe and accurate medicine use, adverse event reporting and medicine recall system. b. Infrastructure supports the maintenance of temperature and humidity where medicines are stored (both within pharmacy as well as outside pharmacy such as nursing units, Operating Rooms etc.) c. Temperature and humidity are documented at least once per shift (all storage areas across the hospital)			

	d. Staff is aware about the actions or SOP to be followed if temperature and humidity is out of range for a substantial period of time e. Medicines requiring cold chain (2-8^{0}C) are adequately monitored across the hospital to avoid temperature excursions f. Proper infrastructure, equipment and systems are in place for specialized pharmacy services such as sterile or non-sterile compounding and chemo admixture etc. g. All the equipment used in pharmacy/hospital undergo periodic preventive maintenance, calibration and validation (as applicable).			
4.	a. Pharmacy & Therapeutics Committee / Drug & Therapeutic Committee and Tender /Purchase committee is established in the hospital. b. Pharmacists have a proper representation in the P&TC/D&TC according to the membership requirements stated (or equivalent committee) in addition to physician and nurse representation. c. Terms of References (ToRs) of the committee are defined, in line with those given in this document and address all basic roles. d. P&TC (or equivalent committee) meets on regular basis. e. Pharmacy/hospital maintains a current list of available medicines in the hospital (Hospital Formulary).			
5.	a. Pharmacy services are available 24/7. b. If Pharmacy services are not available 24/7, then medicines are provided to the nursing units for off-hours use also assuring round the clock essential and emergency services. c. SOPs are defined for the medicines' security, safety, use and replenishment at the nursing units during off-hours use (when pharmacy is closed). d. There is pharmacy oversight on the medicines stored in patient care areas (outside pharmacy) and such stocks are regularly checked for quantity in hand, expiry, lot #, compliance to storage parameters and security conditions etc. e. Medicines are kept in authorized access only (all storage areas across the hospital) f. Medicines are protected from theft and loss in all storage areas across the hospital g. All incoming (purchased, stock in hand, donations etc.) and outgoing supplies (dispensed, returned, disposed etc.) are recorded and reconciled. h. Medicines are periodically counted and accounted for in			

	all storage areas to ensure safety and security of the stocks. i. Expiry of medicines is periodically checked in all storage areas across the hospital to avoid use of expired medicines and wastage. j. Pharmacy inspection is documented.			
6.	a. Traceability of medications from the point of receiving in the hospital till the administration, is possible (for the effective drug recall). b. All medicines used in pharmacy are properly labelled as per standards in the document. c. Controlled drugs are stored securely, with required documentation and are regularly accounted for. d. Issuance, ordering, use, wastage and purchase record of controlled drugs is maintained as per law. e. Staff, handling chemicals and hazardous/chemo drugs, is aware about personal protective equipment (PPEs), Material Safety Data Sheet (MSDS) and spill management			
7.	a. There is a collaborative mechanism to develop and approve the list of medicines that will be available in-patient care areas, outside pharmacy (i.e. on nursing units par level / floor stocks, emergency supplies like crash carts, Anesthesia or CPR trolleys etc.) b. Pharmacists, nurses and physicians are part of the collaborative process (as per point above) c. The emergency supplies like crash carts or CPR trolleys etc. are standardized to have uniform content and placement across the hospital d. Pharmacists, nurses and physicians are part of the emergency supplies standardization (as per point above)			
8.	a. Medicine orders/prescription are reviewed for appropriateness by a pharmacist before administration. All orders including those medicines used from floor stock, medicines used in operating rooms, interventional suites (like radiology, cath lab etc.) and during code blue/CPR) b. Pharmacists are trained in performing appropriateness review c. Minimum contents of appropriateness review are defined by pharmacy/hospital, such as appropriateness of drug, dose, route, frequency and duration of therapy. d. Contraindications (related to patient's diagnosis, co-morbidity, concurrent drugs i.e. drug interactions, and any known drug or food allergies etc.) e. Variation from organization's criteria for use or policy f. Patient's weight and other physiological information g. If any problem is identified in the order, pharmacists discuss with the prescriber and rectify them before			

	dispensing. h. Corrections (interventions) are documented i. Medicines are only dispensed against a proper physician's order/requisition. j. Medication administration timings are standardized across the hospital, and mutually approved by a group (e.g. P&TC) comprising of pharmacists, nurses and physicians e.g. TID means three times a day (6am, 2pm, 10pm), BID or BD means two times a day (10am and 10pm). k. Minimum contents of a prescription are identified and are standardized across the hospital. e.g. patient identification (name and medical record #), patient information (age, gender, weight, diagnosis, drug allergy), medicine order (drug name, dose, route, frequency, duration and special instructions if any), prescriber's identification, Date / prescription validity			
9.	a. Hospital-specific list of high alert medicines (HAMs) is available and is in line with DRAP's High risk medicines list and guidelines. b. HAMs are known to all healthcare staff (physicians, nurses, allied health and pharmacist) c. A hospital-wide policy on safe use and handling of high alert medicines is available. The policy is periodically revised. d. Pharmacy provides pre-diluted, ready-to-use forms of concentrated electrolytes listed on the national HAMs list. e. Pharmacy has an SOP to store and dispense Look-Alike, Sound-Alike (LASA) and Read Alike drugs (LASARA).			
10.	Drug information resources (such as books, pocket guides, charts, flyers, posters, software, or a helpline etc.) are available across the hospital for the physicians, nurses and pharmacists, to easily check the medicines related information when in doubt.			
11	a. Pharmacy Staff orientation and training program (both for pharmacists and non-pharmacists) is available (at the time of induction, ongoing In-service education and training, special trainings on need basis b. Pharmacy staff competency assessment is conducted before placing them in the area of work and periodically at the specified intervals. c. Performance evaluation of pharmacy staff is conducted at a specified interval and is documented			

12	a. There is a hospital-based program of reporting, analyzing and mitigating the Adverse Drug Events (ADEs) i.e. medication errors and near misses. Pharmacist is always involved in the aforementioned processes. b. Pharmacy maintains a record of all dispensing errors and near miss. c. Corrective and preventive actions are taken on these errors/near miss. There is a hospital based program of reporting, analyzing and mitigating the Adverse Drug Reactions (ADRs) as per the Pharmacovigilance Rules 2022 and explained further in Guidelines on National Pharmacovigilance System). d. Pharmacy/Hospital has a well-defined process of product recall. Recalls are timely and documented			

24

Annexure–II

Pharmacy & Therapeutic Committee

Terms of Reference

1.0 Committee Mandate
2.0 Detailed Objectives
3.0 Membership
4.0 Reporting relationship
5.0 Meeting Schedule
6.0 Antibiotic Subcommittee
7.0 Immunization Subcommittee

1.0 Committee Mandate:

The Pharmacy and Therapeutic Committee is an advisory group composed chiefly of physicians, pharmacists, nurses, and representatives from various departments of the hospital. The committee serves as the organizational line of communication between the Medical Staff and the Pharmacy Department. The committee is a policy recommending body to the medical staff and to hospital administration on all matters related to the therapeutic use of drugs within the hospital and its clinics. The committee members are proposed by the respective Chair/ Director and approved by the Hospital administrative/advisory Committee.

2.0 Detailed Objectives:

The primary purposes of the Pharmacy and Therapeutic Committee are:

2.1 Administrative

The committee establishes administrative policies regarding evaluation, procurement, distribution, use safe practices and other matters pertinent to drugs in the hospital and clinics and offsite clinics. The Committee oversees the overall Medication Usage system within the organization.

2.2 Educational

The committee recommends and assists in the formulation of programs designed to meet the needs of the professional staff (doctors, pharmacists and nurses) for complete current knowledge on matters related to drugs and drug prescribing practices.

2.3 Advisory

The committee serves in an advisory capacity to the medical staff and other groups in the establishment of broad policies relating to drug usage in patient care and hospital procedures.

2.4 Functions of the Committee:

- To develop and approve a Drug Formulary for the hospital and provide for its continual revision and update
- To evaluate suggestions of drugs/agents proposed for addition to/deletion from the hospital formulary on generic basis.
- To minimize duplication of the same basic drug type &to recommend additions and deletions (removal of drug (s) in the pharmacy inventory.
- To make and/or consider recommendations concerning drugs to be stocked in hospital patient units or services.

- To study problems related to the distribution and administration of medication.
- To recommend policies regarding the safe use of drugs in the hospital, including investigational drugs and hazardous drugs.
- The scope of the functions is limited to formulary? Either the title be changed from functions to management of formulary. Otherwise scope of functions be extended.

3.0 Membership:

The P&T Committee membership consists of representatives from Medicine, Surgery, Pediatrics and other clinical services, Pharmacy, Hospital Administration and Nursing Services. Chairman & co-chair will be appointed among the physician representatives by the Hospital In charge (MS, CEO etc.) with Hospital Administrative/Advisory Committee approval. Pharmacist will also be the Secretary of the Committee. The Pharmacy and Therapeutic Committee will utilize the clinical experts, as appropriate, to consider specific changes, additions and deletions to the formulary.

Members Representation:

- Internal Medicine
- Family Medicine
- Cancer Care
- Anesthesiology, OT, CSSD
- GI & Surgery
- Obs/Gynecology
- 24/7 Emergency Medicine
- Pediatrics
- Pharmacy
- Nursing Services
- Representative from intensive/critical care unit
- Representative from internal quality audit

4.0 Reporting Relationship:

Recommendations and minutes of the Pharmacy and Therapeutic Committee shall be forwarded to the Committee of the Hospital for their review and acceptance.

5.0 Meeting Schedule:

The P&T Committee may meet at least every month or as necessary. Goals and objectives for coming year will be discussed in the December meeting. In the January meeting the previous year's performance will be discussed for submission. Some of the regular/periodic agenda of P & TC include: medication errors/near miss, ADR reports, medication safety alerts and formulary review.

6.0 Antibiotic Subcommittee

This is subcommittee of P & TC that is overseeing the antibiotic usage, rational antibiotic prescribing and safety of antimicrobial usage in the organization. It assists P & TC in devising safety and medication use related policies specifically related to antimicrobials. Another important mandate of the subcommittee is to revise and publish the Antimicrobial Guidelines to facilitate staff education, knowledge on safe and rational usage.

- The subcommittee meets every month or more frequently as needed. The main agenda items of this subcommittee include: Drug Utilization Evaluation, Antimicrobial formulary review, ADR review pertaining to antimicrobials etc.
- Minutes of this subcommittee is presented to P & TC for review and approval.
- The member representatives of this subcommittee include:
    - Internal Medicine
        - Cancer Care
        - Infection Disease (adult)
    - GI and Surgery
    - Pediatrics
    - Laboratory
    - Pharmacy
    - Nursing Services

7.0 Immunization Subcommittee

This is subcommittee of P & TC that is overseeing the vaccines and immunoglobulin usage, rational prescribing and importance of infection preventive strategies in the organization. It assists P & TC in devising safety and medication use related policies specifically related to vaccines. Another important mandate of the subcommittee is to keep updated formulary of vaccine and immunoglobulin with approved backup products in case of shortage or dry periods.

The subcommittee meets every quarter or more frequently as needed. The scope of the sub-committee may include discussion on the following:

- Vaccine formulary management, ADR review pertaining to vaccines etc.
- Collaborating with EPI for essential vaccines administration and record keeping
- Minutes of this subcommittee is presented to P & TC for review and approval.

- The member representatives of this subcommittee include:
- Infectious disease
- Infection control
- Nursing services
- Pharmacy

Annexure–III

Sample Job Description

Job Identification

Document No:	
Designation	**Chief of Pharmacy / Director Pharmacy / Head of Pharmacy etc. (as applicable)**
Category	Management Staff
Reports to	Chief Operating Officer / Medical Director etc. (as applicable)
Department	Pharmacy

Job Specification

Qualification	**Basic**: Bachelors in Pharmacy or Doctor of Pharmacy from recognized institute Master's degree (or above) relevant to the hospital & clinical pharmacy practice/healthcare management shall be preferred.

Skills:

- Excellent interpersonal, communication and presentation skills.
- Leadership and team-building skills
- Strong analytical & critical reasoning skills.
- Good financial and business acumen.
- Ability of multi-tasking and time management (meeting deadlines under pressure).
- Ability to work independently, exercise creativity, be attentive to detail, and maintain a positive attitude.
- Excellent negotiating and influencing skills.
- Computer skills including the use of MS Office (Word/Excel/ PowerPoint), online meeting and webinar forums (e.g. Zoom, Google Meet, Microsoft Teams etc.)

Knowledge:

- Sound clinical and professional pharmacy knowledge
- Demonstrate understanding and commitment to equality and diversity principles.
- Good knowledge of key health policies, development goals and local bylaws/regulation.
- Knowledge of applicable governmental regulations and compliance requirements.
- A good understanding of international best practices and about some accrediting bodies such as Joint Commission International's or ISO Standards.
- Excellent understanding of Financial, human resources and facility management as it relates to the delivery of health care services.
- Knowledge of Principles of professional pharmacy practice that optimizes patient care.
- Knowledgeable about Healthcare informatics/technology and health information management systems (HMIS) and pharmaceutical supply chain

Personal Attributes:

- Dynamic, passionate, open, participative, and supportive leadership style.
- Exhibits energy, enthusiasm, and resilience to drive through and achieve end results.
- Evidence of innovation and creative strategic thinking ability.
- Ability to manage conflicting priorities, work under pressure, and meet deadlines.
- Demonstrate integrity and high ethical moral behavior
- Possess credibility and commitment to the corporate mission.
- Resilience and adaptability

Registration / License	Provincial Pharmacy Council of Pakistan
Experience (No. of Years)	**8-10 years**

Job Summary:

Chief of Pharmacy is responsible for the overall operational and strategic management of the Pharmacy department andprovides facilitation and administrative leadership by directly supervising the functions of the Pharmacy department.

General Job Responsibilities:

a. Review, update and ensure compliance with the departmental policies and procedures and applicable rules and regulations as set by the regulatory authorities
b. Creates a safe, functional, and comfortable physical environment for patients through extensive coordination with other/concerned departments, and addresses the inefficiencies or delays in the processes (where required).
c. Develops, implements, and evaluates short and long-term goals, objectives, policies and procedures to ensure consistency with organizational goals.
d. Ensures implementation and continuous monitoring of Departmental Key Performance Indicators and objectives.
e. Handling customer complaints; patient care issues, problems, and concerns and taking corrective action where necessary.
f. Be actively involved in the organization's strategic planning regarding all components of the medication management process across the continuum of care
g. Represent and uphold medication management and use standards & medication safety principles in all the relevant forums and committees (within and outside hospital)
h. Maintain good working relationships with the external key stakeholders like manufacturers/suppliers, regulatory authorities, academia and pharmacy council etc.
i. Maintain good working relationships with the internal key stakeholders like purchase, medical & surgical specialties, doctors, nurses, allied health staff, human resources department, IT department, finance and facility management department etc.
j. Ensure processes are in place to identify risks and process to mitigate the risks (risks related to financial, legal, patient safety, staff, visitors etc.).

PHARMACY SERVICES:

a. Organizing, directing, monitoring & managing scope of pharmacy services including: Drug Distribution, electronic prescribing system, Inpatient drug distribution, Cytotoxic Drug Admixture, Intravenous Piggyback system, TotalParental Nutrition Service, compounding, clinical and specialty based pharmacy services, drug information service, Ambulatory Care pharmacy, Emergency pharmacy, pharmacy home care services and others as applicable
b. Organize, develop and manage pharmacy services as per the best practices and Minimum Standards of the Hospital Pharmacy Service (approved by DRAP)
c. Actively work to improve the safety of High Alert Medicines in the organization as per the National High Alert Medicines Guidelines Pakistan (approved by DRAP)
d. Actively work to develop and implement Pharmacovigilance (PV) system in the organization as per the National PV Rules (approved by DRAP)
e. To work in multidisciplinary teams of physicians, nursing and other healthcare professionals and patients to ensure medication safety, compliance to hospital-approved medication use criteria/policies/guidelines, cost-effectiveness andpatient compliance
f. Maximize the use of automation and technology to provide safe, speedy, optimal patient care and/or improve operationalefficiencies.
g. Establish medication management and use in accordance with the recommendations of Pharmacy & Therapeutics Committee and manage andcontrol the hospital formulary system.
h. Establish quality specification & selection criteria for all drugs and chemicals used in accordance with therecommendation of the P&T committee.
i. To plan, establish and oversee clinical pharmacy services and appropriateness review to ensure medicines are issuedand used in a safe, timely and efficient manner and that protocols

utilized are evidence-based and patient-focused.

j. To establish medication error/near miss reporting, ADR monitoring system, drug utilization evaluations and clinical auditwith a focus to use data for improvement of patient safety and service improvisation.
k. Serve as a medicine expert and provide consultation and professional assistance in the development of medication-related guidelines, SOPs and protocols across the hospital.
l. Development of strategic plans for the pharmacy services to ensure the services provided are progressive, responsive tointernal & external demand, patient-focused, efficient and effective.
m. Ensure efficient & effective management of Inventory Control systems. Ensure availability of critical supplies.
n. Develop and update staffing plans and contingency plans for pharmacy department.
o. Conduct regular staff appraisals and provide feedback on their performance against the set criteria/standard and/or define job description.
p. Fulfilling the organization's research and educational missions and upholding the professional pharmacy practices.
q. Works in close collaboration with associated college/university for the smooth rotation and trainings of the under and post graduate pharmacy students (Pharm.D, MPhil)

BUDGETARY, PERFORMANCE & RESOURCE MANAGEMENT:

a. In coordination with Division Managers, ensures appropriate staffing as per regulatory and hospital policies.
b. Conduct Business Variance Report analysis for the department/ section. Identify, develops, and monitor systems forimprovements.
c. Maintain a high level of staff morale, team spirit and job satisfaction among members of a multidisciplinary team.
d. Provide visible and accessible site leadership creating a climate where individuals understand their roles andresponsibilities and people are empowered to be effective in their roles.
e. Oversees and supports talent development of the senior team members to ensure succession planning, mentorship, and coaching within the departments resulting in efficiency & effectiveness in their respective areas.
f. Manage the budget in line to ensure the best use of resources to maximize patient care.
g. Identify and prioritize the business processes to integrate the cost-effective approach and improve productivity.
h. Determine fiscal requirements of the department and prepare budgetary recommendations.

EDUCATIONAL ACTIVITIES:

a. Ensure that all new staff in the department receives an adequate orientation and induction program, having clear understanding of their duties, responsibilities and standards of performance.
b. Directs the development and implementation of ongoing in-service training programs.
c. Provide professional and personal development opportunities for staff.
d. Development and implementation of an enhanced staff competence assessment relevant to their specialties.
e. Promote a culture where individuals and teams are encouraged to develop personal and professional knowledge andskills.

COMMITTEE MEETINGS:

a. Conducts and/or participates in a variety of staff and committee meetings; serves on task forces as assigned.
b. Participate in various hospital Committees and relevant meetings of management (e.g. Pharmacy & Therapeutic, pharmaceutical purchase committee, IT meetings, JCIA/ISO related taskforces, Infection prevention & control, Antibiotic Stewardship committee etc.)

VARIATION OF DUTIES:

The duties and Responsibilities described above do not construe as a complete and exhaustive

list. Duties and responsibilities may be amended from time to time in consultation with the employee to meet any changing conditions and service requirements.

Others:

Any additional task assigned by the CEO/COO/Medical director etc. (as applicable).

Prepared by:	**HR Representative**	
Endorsed by:	**HOD/Divisional Head**	
Approved by:	**Head HR Division**	

Annexure–IV

IMPORTANT POLICIES FOR HOSPITAL PHARMACY

Sample List

1.	High Alert medicines policy
2.	Look-alike & sound-alike (LASA) medicines policy
3.	Antibiotic stewardship/rational antibiotic use policy
4.	Hazardous drugs handling and disposal policy
5.	Pharmacy and Therapeutics committee (P&TC) Terms of References (ToRs)
6.	Formulary management policy
7.	Medicine/surgical shortage management policy
8.	Lifesaving/emergency medicines & surgical stock management policy
9.	Procurement of drugs and surgical supplies policy (for routine, Local/Emergency purchase)
10.	Receiving the drugs / supplies from supplier policy
11.	Vendors & Supplier review and evaluation (for routine, Local/Emergency purchase)
12.	Local/Emergency purchases of medicine and surgical supplies policy
13.	Distribution of Medicines and Supplies /Delivery of indent policy
14.	Safe and secure storage of medicines/surgical policy (within and out of pharmacy)
15.	Temperature (Cool/Ambient) & Humidity monitoring policy
16.	Floor stock management policy (including ward stocks, crash carts and OT supplies etc.)
17.	Prescribing privileges for selected medicines
18.	Safe medicine prescribing and transcribing policy
19.	Elements of complete order or prescription policy
20.	Appropriateness review of the physician order/prescription policy
21.	Pharmacist intervention Record policy
22.	Answering drug and poison information queries policy
23.	Medicine dispensing protocol / procedure (for inpatient, outpatient, ER, others)
24.	Medicine compounding policy (Non-sterile compounding)
25.	Medicine compounding policy & Aseptic checks (Sterile compounding)
26.	Safe medication preparation procedure (for nurses)
27.	Safe medication administration procedure (for nurses)
28.	Standard drug administration timings (e.g. QD = 10am, HS = 10pm)
29.	Policy on the save and reuse of multi-dose medicine containers
30.	Medication/supplies return (refund) policy
31.	Patient counseling and education policy
32.	Over the counter (OTC) drug dispensing policy
33.	Narcotic handling and dispensing policy
34.	Non-narcotic controlled drugs handling and dispensing policy
35.	Adverse Drug Reaction (ADR) reporting and analysis policy
36.	Medication error and near miss reporting and analysis policy
37.	Drug/Device recall policy
38.	Non-formulary drug and surgical request management policy
39.	Pharmacy revenue collection policy
40.	Unclaimed medicines policy
41.	Annual and periodic inventory/perpetual and stock management policy
42.	Stock Expiry and Aging monitoring policy
43.	Management of expired, outdated, wasted medications/surgical supplies policy
44.	Document records and retention period policy
45.	Patient own / patient-brought medications policy
46.	Use of sample medicines / surgical policy

47.	Investigational drug use policy
48.	Clinical Pharmacy quality indicators (e.g. pharmacist interventions, # of ADRs reported etc.)
49.	Pharmacy operational quality indicators (e.g. delays, satisfaction, wastage etc.)
50.	Scope of Pharmacy Services
51.	Staffing plan of pharmacy services
52.	Disaster management plan for pharmacy and continuity of service
53.	Pharmacy organogram
54.	Pharmacy staff orientation, in-service training and development plan

297

298 **Note:**

299 This is a sample list only and not inclusive of all the required pol

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