PHARMACY STANDARDS

STANDARD

Department: Quality Improvement Department

Document Identifier: SD/PH/001/02

STANDARD – PHARMACY STANDARDS

1. PURPOSE	
1.1	These Standards define the requirements to ensure acceptable minimum levels of quality, performance, safety and reliability of pharmacies and pharmacy services in Dubai Healthcare City (DHCC). It describes the types of pharmacies that may operate and includes standard requirements for obtaining and maintaining status as a Licensed Pharmacy within DHCC.

2. SCOPE OF APPLICATION	
2.1	These Standards are applicable to all Licensed Pharmacies and healthcare operators providing pharmacy services licensed by Dubai Healthcare City Authority (DHCA) for a Clinical Operating Permit to operate a Pharmacy.
2.2	These standards are also applicable to DHCR personnel involved in the regulator activity for Pharmacies and pharmacy services.

3. STANDARD	
3.1	**LICENSURE OF PHARMACIES**
3.1.1	Any DHCC Entity wishing to provide Pharmacy Services shall be licensed by Dubai Healthcare City Authority in accordance with the requirements and procedures of the DHCA Healthcare Operators Regulation No. 4 of 2013, the Company Regulation No. 8 of 2013, the Commercial Services Licensing Regulation No. 9 of 2013 and the Standards defined herein.
3.1.2	All entities shall follow the Licensed Pharmacy's DHCR fit-out design compliance submission requirements.
3.1.3	Entities shall comply with the FGI Guidelines for Design and Construction of Health Care Facilities; Pre-Operating/Post-Operating assessment survey checklist and standards.
3.1.4	Each Pharmacy will be licensed as one of the following: 3.1.4.1 Community Pharmacy 3.1.4.2 Community Pharmacy (Compounding) 3.1.4.3 Hospital Pharmacy 3.1.4.4 Inpatient Pharmacy 3.1.4.5 Internal Pharmacy; or 3.1.4.6 Public Service Pharmacy.
3.1.5	**A Licensed Community Pharmacy** is an independent pharmacy that is not affiliated with any other healthcare operator and provides products and medical services, and associated goods to the general public within DHCC.

STANDARD – PHARMACY STANDARDS

3.1.5.1 A Clinical Operating Permit for a Community Pharmacy may be issued to a company registered as a Pharmaceutical Company in accordance with local law and current DHCA regulations.

3.1.5.2 A Licensed Community Pharmacy may trade in other health and cosmetic related products including health foods, children's food, formula milk, sanitary goods, medical, optical and dental products, male and female grooming products, cosmetics and perfumes.

3.1.5.3 A Licensed Community Pharmacy shall first obtain approval for the production and dispensing of sterile compounded medicines prior to offering such products and services from relevant authorities.

3.1.5.4 If a Licensed Pharmacy undertakes Compounding work, depending on the kind of prepared formulation, the Pharmacy must develop a Compounding Policy and Procedure Manual that sets out:

- 3.1.5.4.1 procurement procedures,
- 3.1.5.4.2 methodologies for the formulation and Compounding of preparations;
- 3.1.5.4.3 a plan for facility and equipment cleaning and calibration;
- 3.1.5.4.4 a plan for facility and equipment maintenance and other standard operating procedures of the facility;
- 3.1.5.4.5 validation of the competency and proficiency of all Licensed Pharmacists in the art of Compounding; and
- 3.1.5.4.6 appropriate policies related to venting and exhaust in cases where toxic Compounds or fumes are present.

3.1.5.5 A Licensed Community Pharmacy shall obtain approval from DHCR to operate on a 24-hour basis. Such approval shall be based on community needs and the ability of the Pharmacy to provide and maintain the service adequately and continually.

3.1.5.6 A Licensed Community Pharmacy or its employees may not enter into agreements with physicians or other individuals concerning the preferential supply of pharmaceuticals, favored receipt of prescriptions or referral of patients or were such agreements are for the supply of ready-to-use chemotherapeutic drugs for specific patients.

3.1.5.7 A Licensed Community Pharmacy may enter in to legal agreement to supply medicines and pharmaceutical products to residents of Licensed Nursing Homes within DHCC subject to the authorization by DHCR. Such authorization shall be provided subject to:

- 3.5.7.1 The responsibilities of the Pharmacist-In-Charge extending to the pharmacy services provided in the Licensed Nursing Home being clearly stipulated in the agreement;
- 3.5.7.2 The responsibilities of the Licensed Pharmacist(s) regarding the provision of information, consultation and care extending to the residents of the Nursing Home being stipulated in the agreement;

	3.5.7.3 The agreement does not restrict the rights of the residents of the Nursing Home to make a choice of a pharmacy for their needs; 3.5.7.4 The agreement does not provide an exclusivity right to the Pharmacy to supply such medicines and pharmaceutical products to the Nursing Home.
3.1.6	**A Licensed Hospital Pharmacy** is a pharmacy located within a hospital which provides medicines, pharmaceutical products and services to inpatients and outpatients of the hospital and may dispense medications for use after discharge of the patient. 3.1.6.1 A Clinical Operating Permit for a Hospital Pharmacy may be issued to a DHCA Entity that holds a Clinical Operating Permit for a Hospital. 3.1.6.2 A Hospital Pharmacy may not sell any other products or goods other than medicines and pharmaceutical products prescribed to hospital patients. 3.1.6.3 A Licensed Hospital Pharmacy shall not provide pharmaceutical products and services to the general public with the following exceptions: 3.1.6.3.1 In the provisions of prescribed controlled drugs or narcotics; 3.1.6.3.2 In the provision of prescribed chemotherapeutic and cytotoxic drugs; 3.1.6.3.3 In the provision of prescription only drugs which are not easily available in the general market.
3.1.7	**A Licensed Inpatient Pharmacy** is a pharmacy located within an Inpatient Facility which is not a hospital, and may be a Licensed Hospice, Nursing Home, Inpatient Rehabilitation Center or Outpatient Surgical Clinic. A Licensed Inpatient Pharmacy provides medicines and pharmaceutical products, and services to meet immediate or current requirements for the care solely of patients of the Healthcare Operator. 3.1.7.1 A Clinical Operating Permit for an Inpatient Pharmacy may be issued to a DHCA Entity that holds a Clinical Operating Permit for one of the types of Healthcare Operators listed in 3.1.5. 3.1.7.2 A Licensed Inpatient Pharmacy may compound and dispense medicines and pharmaceuticals for the ongoing care of an inpatient; for pre-procedural purposes, e.g. antibiotic prophylaxis, VTE prophylaxis, pre-colonoscopy laxatives, etc.; for peri-procedural purposes, e.g. sedatives, anesthetics and analgesics; and/or for post-procedural purposes, e.g. antibiotics, wound treatment ointments, etc. 3.1.7.3 A Licensed Inpatient Pharmacy shall not provide pharmaceutical products and services to the general public. 3.1.7.4 A Licensed Inpatient Pharmacy may not sell or provide other products or goods other than medicines and pharmaceutical products prescribed for the immediate or current treatment of the patient as per 3.1.5.
3.1.8	**A Licensed Public Service Pharmacy** is a pharmacy located within or affiliated with a government body, a public authority or a public institution and which provides medicines and pharmaceutical products, and services to patients and/or employees of the affiliated government body or institution.

STANDARD – PHARMACY STANDARDS

	3.1.8.1 A Clinical Operating Permit for a Public Service Pharmacy may be issued to a DHCA Entity that is registered as a government body, a public authority or a public institution and demonstrates a need for a pharmacy to operate on their premises. 3.1.8.2 A Licensed Public Service Pharmacy shall not provide pharmaceutical products and services to the general public. 3.1.8.3 A Public Service Pharmacy may not sell or provide any other products or goods other than medicines and pharmaceutical products prescribed to patients or employees of the affiliated body or authority.
3.1.9	**ALL LICENSED PHARMACIES**
3.1.9.1	Each Licensed Pharmacy shall in accordance with their scope of services: 3.1.9.1.1 Be responsible for ensuring an adequate supply of medicines and pharmaceutical products to meet the needs of the population being served. 3.1.9.1.2 Not enter in to agreements that lead to preferential use of certain medicines or pharmaceutical products, or that inhibits or limits the choice of medicines to particular manufacturers or distributors. 3.1.9.1.3 Prominently display a copy of its Clinical Operating Permit in public accessible areas, 3.1.9.1.4 Maintain and keep their premises in a clean and sanitary condition; 3.1.9.1.5 Have counseling areas and waiting areas that, if present, contain adequate patient resource material or other healthcare related information, and have seating, if required, for patients and family members; and 3.1.9.1.6 a dispensary area that: 3.1.9.1.6.1 is well ventilated and contains sufficient lighting; 3.1.9.1.6.2 is visible and easily identifiable to the patients; 3.1.9.1.6.3 contains no Products inappropriate to the Practice of Pharmacy; 3.1.9.1.6.4 contains a prescription counter area; 3.1.9.1.6.5 contains sterile water for the preparation of Products stored in areas in which Products are compounded; and 3.1.9.1.6.6 counselling areas that are located in a private or semi-private area that is sufficiently secure to protect patient privacy and confidentiality.
3.1.9.2	**For security requirements, each Pharmacy must:** 3.1.9.2.1 install and maintain windows and doors that are equipped with secure locks and shall be locked in the absence of a Licensed Pharmacist on that premises; 3.1.9.2.2 install and maintain a security alarm that shall be utilized after hours or anytime that the Licensed Pharmacy is closed; and 3.1.9.2.3 have a Pharmacist in Charge who is responsible for the security of medications.

STANDARD – PHARMACY STANDARDS

3.1.9.3	**Narcotics and Controlled Drugs Management** 3.1.9.3.1 The pharmacy shall develop their own policies and procedures for the management of narcotics and/or controlled medicines, in accordance with Federal and Local Laws which clearly identify roles and responsibilities. 3.1.9.3.2 The pharmacy shall seek approval to procure, store, prescribe, dispense and administer from the Ministry of Health and Prevention (MOHAP).

3.2	**QUALIFIED PERSONNEL**
3.2.1	Each Licensed Pharmacy shall appoint and maintain adequate numbers of qualified Licensed Pharmacists and Licensed Pharmacy Technicians to ensure reliable and consistent services in compliance with these Standards, any approved codes of practice (ACOP) pertaining to pharmacies any Quality Oversight Policies, and any other applicable regulations, rules and standards issued by DHCR or Ministry of Health and Prevention (MOHAP).
3.2.2	Each Licensed Community Pharmacy which is approved to provide 24 hour services shall appoint and maintain qualified Licensed Pharmacists to provide such services with adequate relief staff to account for vacations and sickness.
3.2.3	Pharmacists and Licensed Pharmacy Technicians providing Pharmacy Services shall be Licensed Healthcare Professionals in DHCC.
3.2.4	Pharmacist in charge 3.2.4.1 Each Licensed Pharmacy shall appoint a permanent Pharmacist-in-Charge who shall be a DHCA Licensed Pharmacist in good standing and who shall be registered with DHCR as the appointed Pharmacist-in-Charge within 14 days of appointment. 3.2.4.2 DHCR shall be notified of any change to the Pharmacist-In-Charge including temporary absence for a period more than 14 days. 3.2.4.3 In the absence of the Pharmacist-in-Charge for any period greater than 14 days, a Licensed Pharmacist shall be appointed in an acting position. 3.2.4.4 The name, license number and license expiry date of the Pharmacist-In-Charge shall be prominently displayed in the pharmacy against the title of 'Pharmacist-in-Charge'. 3.2.4.5 The Pharmacist-in-Charge shall be responsible for compliance to all laws, regulations, policies and standards pertaining to the operation and practice of Pharmacy in DHCC. 3.2.4.6 The Pharmacist-in-Charge shall be the named responsible person and the designated signatory for the management of controlled drugs. 3.2.4.7 The Pharmacist-in-Charge shall have unhindered access to the Pharmacy at all times and upon the request of authorized employees of DHCA, the police or other relevant government departments or officials with jurisdiction in DHCC. 3.2.4.8 The Pharmacist-in-Charge shall be responsible for all operational activities conducted within the pharmacy including but not limited to:

STANDARD – PHARMACY STANDARDS

	3.2.4.8.1 ensuring that the procurement of medicines is conducted in a transparent and ethical manner that allows the traceability of the source of all products; 3.2.4.8.2 implementation and oversight of a quality assurance process that assures that substandard, adulterated, unlicensed, or inaccurately labelled, falsified, illegal, of unknown origin and counterfeit medicines are not procured or enter the pharmacy system; 3.2.4.8.3 ensuring contingency plans for medicine shortages; 3.2.4.8.4 the secure and proper storage of all medicines, including controlled substances; 3.2.4.8.5 monitoring drug and medication recall notices, and the prompt and effective action to recall provided drugs, medicines and medical products known or suspected to pose a risk to patients and the general public; 3.2.4.8.6 ensuring all procedures at the Licensed Pharmacy are carried out by a Licensed Pharmacist or, a Licensed Pharmacy Technician under the supervision of a Licensed Pharmacist; 3.2.4.8.7 the overall supervision of the conduct and practices of all Licensed Pharmacists and Pharmacy Technicians; 3.2.4.8.8 establishing and maintaining a system for pharmacovigilance including reporting and investigating medication errors at any stage of the pharmacy processes; and 3.2.4.8.9 establishing and maintaining a system for reporting adverse events including reporting and investigation.
3.2.5	Each Licensed Pharmacy must be under the personal supervision of a Licensed Pharmacist during all operational times.
3.2.6	The name(s), License details and title(s) of the pharmacist(s) and pharmacy technician(s) who is/are on duty are to be prominently displayed.
3.2.7	The ratio of Licensed Pharmacists to Licensed Pharmacy Technicians shall not be less than one (1) Licensed Pharmacist for every two (2) Licensed Pharmacy Technicians.
3.2.8	Each Licensed Pharmacist and Licensed Pharmacy Technician shall have current personal indemnity insurance.
3.2.9	Only Licensed Pharmacists and Licensed Pharmacy Technicians may dispense, sell or provide medicines and pharmacy services that would otherwise not be available except from a Licensed Pharmacy.
3.2.10	Each employee in the pharmacy shall wear an identification badge with their name, name of pharmacy and respective job title clearly displayed.

3.3	**PHARMACY MANAGEMENT**
	Each Licensed Pharmacy shall:

STANDARD – PHARMACY STANDARDS

3.3.1	Be managed in accordance with these Standards, DHCA Approved Codes of Practice and all other applicable laws, regulations, policies and standards.
3.3.2	Establish effective written Policies and procedures and maintain adequate records regarding the obtaining, procuring, storage, securing, labelling, pricing, dispensing, disposal and accountability of medications and pharmaceutical products in accordance with their scope of services and the scope of their licensed professionals.
3.3.3	Ensure that all medicines and pharmaceutical products are dispensed, sold or distributed in accordance with the recognized Dispensing Mode for each item as listed from time-to-time by the MOHAP.
3.3.4	Receive prescription orders manually or by use of a facsimile machine, computerized physician order entry mechanism, electronic hand-held device or other electronic transmission from the prescribing physician to the Licensed Pharmacy.
3.3.5	Ensure that where a Licensed Pharmacist it employs receives a prescription order by electronic transmission, the Licensed Pharmacist uses professional judgment to determine its accuracy, validity, and authenticity. In cases where the accuracy, validity or authenticity is in question, the Licensed Pharmacist shall contact the prescribing physician directly, all such communications shall be documented.
3.3.6	Have a process to ensure a review of all prescriptions and orders of medicines, including patient requests for PH-OM medicines, for appropriateness prior to dispensing to include: 3.3.6.1 the appropriateness of the drug, dose, frequency, and route of administration; 3.3.6.2 drug disease contraindication; 3.3.6.3 potential drug therapy problems due to therapeutic duplication; 3.3.6.4 potential interactions between the medication and other medications and food stuffs; 3.3.6.5 potential drug allergies; and 3.3.6.6 possible clinical abuse or misuse.
3.3.7	Verify with the prescribing physician all written prescriptions and orders which contain error prone abbreviations, symbols and dose designations as defined by the Institute for Safe Medication Practices (ISMP) prior to dispensing the medications. Such verification shall be documented in the prescription or the patient's record.
3.3.8	Develop and implement written procedures to ensure that each Licensed Pharmacist it employs must, upon discovering an error or omission in a prescription or medicine order: 3.3.8.1 contact the prescribing physician for further clarification; 3.3.8.2 note such clarification on the original prescription or patient's record, including the date, time and name of the Licensed Pharmacist seeking the clarification; and 3.3.8.3 when appropriate, advise the patient of all such changes.
3.3.9	Develop and implement written procedures to ensure that no Licensed Pharmacist or any other personnel may make any changes to a prescription or medication order without prior approval of the prescribing physician, and that:

	3.3.9.1 any approved changes shall be noted on the original prescription or patient's record, including the date, time and name of the Licensed Pharmacist who obtained such change(s) or on whose behalf permission was sought to make such change(s); and 3.3.9.2 all such changes are clearly communicated to the patient.
3.3.10	Have, as appropriate a standardized process for counseling by Licensed Pharmacists to service users, prescribers, clients and patients. Such process may include advice, information and counseling and may incorporate the following: 3.3.10.1 the name and description of the medical product; 3.3.10.2 the appropriateness of medicines for the condition or presenting symptoms; 3.3.10.3 the route of administration, dosage, dosage form and duration of therapy; 3.3.10.4 special instructions or precautions for the preparation, administration or use of the Product by the patient/client; 3.3.10.5 common and severe side effects, interactions and contraindications that may be encountered, including their avoidance and action required if they occur; 3.3.10.6 techniques for self-monitoring drug therapy; 3.3.10.7 proper Product storage; 3.3.10.8 prescription refill information; and 3.3.10.9 any action that should be taken in the event of a missed dose.
3.3.11	Ensure that all information provided to patients, other healthcare professionals and the public is evidence-based, objective, accurate and appropriate. Information provided shall be non-promotional.
3.3.12	Develop and implement procedures to ensure regular monitoring of Product inventory that shall include periodic inspection for expiration dates, spoiled or tampered products and removal of outdated stock.
3.3.13	Develop and implement a recall procedure that can be readily activated to assure within reason that all Products included on the recall, are returned to the pharmacy, removed from the supply chain and are returned to the supplier or otherwise properly disposed.
3.3.14	Establish a safe way for medicine disposal that will encourage and allow patients and the public to return expired or unwanted medicines and medical devices.
3.3.15	Ensure that they prohibit their employees from acquiring Product samples for the purpose of compounding, dispensing, or resale.
3.3.16	Ensure that they develop, implement and monitor the effectiveness of a Policy and Procedure for High Alert Medications including *look alike* and *sound alike* medications.

3.4	**COMMUNITY PHARMACY MANAGEMENT**
3.4.1	Each Licensed Community Pharmacy shall follow all standards as defined in 3.3.1 through 3.3.16.
3.4.2	Each Licensed Community Pharmacy shall in providing counseling services as defined in 3.3.10 include an assessment of the patient's health status and needs. Such assessment shall ensure health

	management, disease prevention and lifestyle behavior and shall be performed with consideration to individuals' education level, cultural beliefs, language and physical and mental capacity.
3.4.3	Pursuant to 3.3.6 as a condition of dispensing a POM classified Product, each Licensed Community Pharmacy shall ensure that the prescription order for the Product contains at least the following information: 3.4.3.1 the full name, and, where possible, address, of the patient; 3.4.3.2 the full name of the Prescribing Professional, a seal bearing his/her name/signature along with the name of the Licensed Facility, his/her license number, signature and the date of issuance of the prescription, in writing; 3.4.3.3 the Product name and/or generic name, strength, dosage and quantity prescribed, frequency and duration of use; 3.4.3.4 instructions for use, including any storage or auxiliary information; and 3.4.3.5 the number of refills authorized.
3.4.4	Each Licensed Community Pharmacy shall ensure that: 3.4.4.1 it maintains sufficient medicines and chemicals to fill, compound or dispense all customary prescriptions; 3.4.4.2 medicines and healthcare Products it offers for sale are approved for sale in the UAE by the MOHAP; 3.4.4.3 POM and PH-OM medicines are not included in window displays or otherwise advertised to the public; 3.4.4.4 POM and PH-OM medicines are not available for self-selection by customers; 3.4.4.5 all medicines are clearly marked with the latest MOHAP approved retail price; 3.4.4.6 all medicines are sold in their original packs. If partial packages are required, then they must carry the medicine name, batch number and expiry date, and the patient must receive (free of charge) a copy of the original package insert or patient leaflet.
3.4.5	All POM drugs dispensed by a Licensed Community Pharmacy to a patient must be labeled with the following information: 3.4.5.1 name, address, and telephone number of the Community Pharmacy; 3.4.5.2 date the prescription is dispensed; 3.4.5.3 full name of the patient; 3.4.5.4 brand name and/or generic name of drug, strength, and number of units; 3.4.5.5 directions for use by the patient; 3.4.5.6 if the drug is dispensed in a container other than the manufacturer's original container, the name of the medication, strength and the date after which the drug should not be used must be indicated on the container.
3.4.6	A Licensed Pharmacist employed by a Community Pharmacy may refuse to fill a prescription if, after appropriate research, he/she believes that the Product to be dispensed:

	3.4.6.1 may be harmful to the patient; 3.4.6.2 is not prescribed according to the Product's approved use, in accordance with an approved list of Product uses developed specifically for use within DHCC, or, if the specific Product is not included on such a list, then by the United States Food and Drug Administration; or 3.4.6.3 if there is a question as to the validity/authenticity/accuracy of the prescription.
3.4.7	A Licensed Pharmacist employed by a Community Pharmacy who receives a prescription for a drug for which there is one or more less expensive generic equivalents available may dispense such generic equivalents if: 3.4.7.1 the patient or their representative is informed that a less expensive generic equivalent is available; 3.4.7.2 the patient or their representative is able to choose between the prescribed brand and the generic equivalent; and 3.4.7.3 the dispensing Pharmacist documents on the prescription that a generically equivalent drug has been dispensed.
3.4.8	The dispensing of generically equivalent drugs may not be performed by a Licensed Pharmacist as per 3.4.6 if: 3.4.8.1 the prescribing physician has indicated in writing on the prescription that no substitution should be made; 3.4.8.2 if the retail price of the generically equivalent drug is the same or of higher price than the prescribed brand drug; or 3.4.8.3 if the prescription is for an immunosuppressant drug.
3.4.9	Each Licensed Community Pharmacy shall comply with all Federal and local laws and regulations for the acquisition, storage, dispensing and disposal of controlled drugs and narcotics.
3.4.10	Controlled drugs and narcotics shall only be dispensed if prescribed on MOHAP controlled drug prescription pads and pursuant to clause 3.4.5.
3.4.11	Dispensing modes are the following: 3.4.11.1 **Medicines by prescription only (POM):** These medicinal products must be dispensed by a licensed pharmacist only upon receiving a prescription from a legitimate healthcare professional. 3.4.11.2 **Medicines restricted to Pharmacist Only (PH-OM):** These medicinal products must be dispensed by a licensed pharmacist, however, a prescription from a healthcare professional is not required, and those products should not be stored in direct access to consumers. 3.4.11.3 **Over the Counter Pharmacy Medicine (OTC-P):** These medicinal products may be dispensed without a prescription and sold only in pharmacies, and such products may be stored in direct access to the consumers.

STANDARD – PHARMACY STANDARDS

	3.4.11.4 **Medicines sold in pharmacy and non-pharmacy outlet (OTC-G):** These medicinal products may be sold in pharmacies and outlets such as supermarkets with controlled storage conditions and the acquisition must be made through a licensed medical store only.

3.5	**HOSPITAL AND INPATIENT PHARMACY MANAGEMENT**
3.5.1	When dispensing medicines prescribed to hospital outpatients or to inpatients at time of discharge such pharmacy services shall be aligned to the standards for a Licensed Community Pharmacy as defined in 3.4.1 to 3.4.11.
3.5.2	Additional requirements Floor or ward stock system: 3.5.2.1 All but the most unusual drug products are stocked on the nursing stations in a floor or ward stock system. Drug products which require special control and management (e.g. high alert, antineoplastic agents) are often omitted from floor stock and are sent to the nursing unit upon receipt of a prescription order for the individual patient. All containers used for floor stock must meet specific labeling requirements as addressed above. 3.5.2.2 Individual prescription order system: 3.5.2.2.1 All medications are dispensed by the Licensed Pharmacist on individual prescription orders in an individual prescription order system. 3.5.2.3 Combination of floor stock and the individual prescription order system: 3.5.2.3.1 Most medications are dispensed on an individual prescription basis. The remaining drugs are obtained via limited floor stock.
3.5.3	Medications should be contained in single unit packages in a unit dose system.
3.5.4	Where possible, medications are dispensed in a ready-to-administer form.
3.5.5	All dose packages must be labeled properly, including the patient's name, strength, expiration date, lot number or control number, or both.
3.5.6	Establish standards and procedures for correct identification of the patient prior to dispensing/administration and medication monitoring.
3.5.7	Each Licensed Hospital Pharmacy shall maintain a written preventive maintenance program for all equipment and related procedures.

3.6	**PUBLIC SERVICE PHARMACY MANAGEMENT**
3.6.1	Each Licensed Public Service Pharmacy when dispensing medicines prescribed to patients or employees of the affiliated body or authority shall meet the standards as specified in section 3.4 of these standards.

3.7	**COMPOUNDING PHARMACY**
3.7.1	To obtain and maintain a Clinical Operating Permit, each Licensed Hospital Pharmacy shall obtain and maintain minimum Compounding and Dispensing equipment and supplies.

STANDARD – PHARMACY STANDARDS

3.7.2	If a Licensed Hospital Pharmacy undertakes Compounding work, depending on the kind of prepared formulation, the Pharmacy must develop a Compounding Policy and Procedure Manual that sets out: 3.7.2.1 procurement procedures; 3.7.2.2 methodologies for the formulation and compounding of preparations; 3.7.2.3 safe and clean compounding area 3.7.2.4 sterile water and chemicals required for compounding 3.7.2.5 The pharmacy must have written policy and procedures that cover 3.7.2.6 Personal protective garments and equipment 3.7.2.7 Handling technique training 3.7.2.8 Aseptic techniques /Preparation including the use of laminar flow hood 3.7.2.9 Storage of sterile/hazardous preparations 3.7.2.10 Labeling including the specification of expiry date 3.7.2.11Cleaning and disinfecting of the compounding areas (hood and work surfaces) 3.7.2.12 Quality assurance for prepared drugs Requirement for hazardous compounding: 3.7.2.13 Hazardous waste collection and disposal 3.7.2.14 Emergency procedures for treating accidental contact 3.7.2.15 Screening for the staff handling cytotoxic preparations 3.7.2.16 Spill management 3.7.2.17 Facilities and equipment cleaning and calibration procedures; maintenance, operation and other standard operating procedures of the facility; 3.7.2.18 A process for the validation of the competency and proficiency in the art of Compounding for all pharmacists; and policies related to venting and exhaust in cases where toxic compounds or fumes are present.

3.8	**GENERAL REQUIREMENTS**
3.8.1	The facility has a valid contract or other alternative arrangements with a third party for pest and rodents control.
3.8.2	The facility temperature is below 25 C, and the relative humidity does not exceed 60%.
3.8.3	The facility has a dedicated pharmaceutical refrigerator (in good working condition) for the storage of temperature sensitive pharmaceutical products and vaccines
3.8.4	Medical products are segregated according to manufacture recommendations (e.g. light sensitive/ heat sensitive/ flammables/ Toxic/ Corrosives etc.)
3.8.5	Pharmacists follow a standard dispensing procedure that ensures double checking of dispensed medications

STANDARD – PHARMACY STANDARDS

3.8.6	The facility has an archiving/ record keeping system related to patient profiling, pharmaceutical records, prescriptions, etc.
3.8.7	The facility has policy and procedure for storage and accessibility of emergency medications / crash cart medications
3.8.8	The facility has policy and procedure for the acquisition of non-formulary items.
3.8.9	Ensure there are policies and procedures in place to handle customer complaints and feedback.
3.8.10	Continuous risk assessment and management are maintained and followed.
3.8.11	Each Licensed Pharmacy shall maintain all of its equipment and supplies and calibrate them regularly to ensure proper functioning.
3.8.12	Each Licensed Pharmacy shall create and retain, for a minimum of three (3) years, records documenting the maintenance of its equipment and supplies.

3.9	**INVESTIGATIONAL DRUGS**
3.9.1	Operators involved in any element of management of investigations drugs must: 3.9.1.1 Establish policies and procedures relevant to the scope of services including but not limited to procurement, storage, preparation, handling and use of Investigational drugs 3.9.1.2 Investigational drugs must be properly labeled and may be administered only under the personal and direct supervision of the principal Licensed Physician-investigator or Licensed Physician-investigator's authorized clinician with prior approval of the appropriate committees of the Hospital and DHCR.
3.9.2	Licensed Health care professionals with relevant scope of practice may administer such drugs only after they have been educated and trained concerning relevant pharmacologic information about such drugs by the Licensed Physician or the Licensed Pharmacist.
3.9.3	A central unit must be maintained wherein essential information regarding such drugs may be obtained. The Informed Consent of patients or representatives must be obtained prior to investigational drug therapy.
3.9.4	No research activities including those involving investigational drug therapy may be conducted in DHCC prior to receiving the necessary approval from the DHCR Research Department, the Academic and Research Council, and the DHCR Research Ethics Committee.

3.10	**INFORMATION MANAGEMENT**
3.10.1	Each Licensed Pharmacy shall establish effective written policies, procedures and maintain adequate records in accordance with the scope of their services including the obtaining, storage, securing, labelling, prescribing, dispensing, administration, monitoring, record keeping, disposal and accountability of

	medicines as appropriate which are in keeping with these Standards and all other applicable laws, regulations and rules.
3.10.2	Records must be kept confidential and comply with the requirements of the DHCC Health Data Protection Regulation No. (7) of 2013. Medical records may only be released in accordance with the provisions outlined in the DHCC Health Data Protection Regulation No. 7 of 2013.
3.10.3	Licensed Pharmacies must comply with MOHAP rules and regulations regarding dispensing, registering and keeping records regarding controlled Products.
3.10.4	The Pharmacist in Charge is responsible for complying with MOHAP record-keeping requirements with respect to controlled Products, referencing the following MOHAP Register Books: 3.10.4.1 Psychotropic Drug Register (also known as the "Registered Prescription", "R.P". "Group 4" medicines. The Register is obtained from the MOHAP after payment of the specified fees, and it shall be labeled "CD-A"/" R.P"/" Group 4"; and 3.10.4.2 Semi-Controlled Drug Register, also known as "Controlled Prescription", "C.P", or "Group 5" medicines. For each item, the Register should record the data and quantity Dispensed. It must be labeled "CD-B"/"C.P"/"Group 5".
3.10.5	A prescription filing system should be developed for controlled medications. The filing system for these medications should separate the Group 4 from the Group 5 prescriptions. The prescriptions should be arranged by prescribing Licensed Physician and by date.
3.10.6	Controlled drug prescriptions must be kept for five (5) years, including a minimum of two (2) years at the Licensed Pharmacy and the remaining three (3) years within a secure storage.
3.10.7	Each Licensed Pharmacist must reconcile the Licensed Pharmacy's inventory of controlled drugs with patient prescriptions that have been dispensed. Any missing items must be reported to the MOHAP Drug Control Department. Delivery documentations from vendors of controlled medications should be filed (according to the agent) and kept for at least twelve (12) months after delivery.
3.10.8	Records of uncontrolled medications are to be maintained and filed for a minimum of five (5) years either electronically or by hard copy.
3.10.9	A general file must be kept in the Licensed Pharmacy which is 3.10.9.1 Part One: Reports, circulars, policies and standards issued by the MOHAP and by DHCC; and 3.10.9.2 Part Two: Copies of DHCC licenses, staff leave and training positions, and Licensed Pharmacy operating procedures.
3.10.11	The Licensed Pharmacy must also maintain a hard copy or electronic pricing file which contains the MOHAP price list.

STANDARD – PHARMACY STANDARDS

3.10.12	All Compounded materials shall be documented on a worksheet log with the following information: 3.10.12.1 Date prepared; 3.10.12.2 Expiry Date assigned to the prepared Product, which shall be allocated as per the compounding guidelines of the product or the manufacturer's Expiry Date, whichever is shorter; 3.10.12.3 Lot or controlled number assigned to the prepared Product; 3.10.12.4 Names ingredients or solutions used, including their respective concentrations, quantity/volume used, manufacturer name, lot numbers and manufacturer Expiry Dates; and 3.10.12.5 The identities of personnel who have prepared the Product and the Licensed Pharmacist who performed the final check.

3.11	**DHCR PROCEDURE**
3.11.1	DHCR Personnel will survey and inspect all licensed pharmacies in accordance with their Standard Operating Procedures to measure compliance with these standards.

4 DEFINITIONS	
4.1	**A Licensed Pharmacy** is a healthcare facility holding a License issued by the Licensing Board in one of the categories stated in these standards to engage in the Practice of Pharmacy in accordance with the Healthcare Operators Regulation and the applicable Rules governing the Practice of Pharmacy.
4.2	**A Licensed Community Pharmacy** is an independent pharmacy that is not affiliated with any other healthcare operator and provides products and medical services, and associated goods to the general public within DHCC.
4.3	**A Licensed Hospital Pharmacy** is a pharmacy located within a hospital which provides medicines, pharmaceutical products and services to inpatients and outpatients of the hospital and may dispense medications for use after discharge of the patient.
4.4	**A Licensed Inpatient Pharmacy** is a pharmacy located within an Inpatient Facility which is not a hospital, and may be a Licensed Hospice, Nursing Home, and Inpatient Rehabilitation Center. A Licensed Inpatient Pharmacy provides medicines and pharmaceutical products, and services to meet immediate or current requirements for the care solely of patients of the Healthcare Operator.
4.5	**A Licensed Public Service Pharmacy** is a pharmacy located within or affiliated with a government body, a public authority or a public institution and which provides medicines and pharmaceutical products, and services to patients and/or employees of the affiliated government body or institution.
4.6	**Internal Pharmacy** is a pharmacy located within an Outpatient Facility (i.e. Multi-specialty clinic, Outpatient Surgical Clinic, etc.). A Licensed Internal Pharmacy provides medicines and pharmaceutical products, and services to meet immediate or current requirements for the care solely of patients of the Healthcare Operator.
4.7	**Compounding**: The combining, mixing, or altering ingredients of a drug to create a medication tailored to the needs of an individual patient through the use of dilution, admixture, repackaging, reconstitution or other manipulation of sterile or non-sterile Products within a Licensed Pharmacy.
4.8	**Community Pharmacy (Compounding):** A licensed pharmacy that is independent and that is not connected to or affiliated with any other healthcare operator. Licensed to prepare, formulate, Compound, dispense, exhibit or sell a medical product directly to customers and according to UAE federal laws and DHCA regulations. It is operated and managed by a licensed pharmacist.

STANDARD – PHARMACY STANDARDS

4.9	**DHCA-R:** Means the Dubai Health Care City Authority – Regulatory
4.10	**Dispensing Mode:** It is the classification of the medicines according to the process of dispensing them.
4.11	**DHCC:** Dubai Healthcare City
4.12	**DHCA:** Dubai Healthcare City Authority
4.13	**DHCA-R:** Means the Dubai Health Care City Authority – Regulatory.
4.14	**Dispensing Mode:** It is the classification of the medicines according to the process of dispensing them**.**
4.15	**Expiry Date**: The expiration date is the final day that the manufacturer guarantees the full potency and safety of a medication. It contains the date (and time, when applicable) beyond which a Product should not be used. The Expiry Date is assigned on the basis of stability and risk level, whichever is the shorter period.
4.16	**FGI:** Facility Guidelines Institute (Guidelines for Design and Construction of Hospital and Outpatient Facilities).
4.17	**Generically equivalent:** a drug that is pharmaceutically equivalent and therapeutically equivalent to the drug prescribed.
4.18	**ISMP:** Institute for Safe Medication Practices.
4.19	**Licensed Healthcare Operator:** Any entity wishing to provide Pharmacy Services and licensed by DHCR in accordance with the requirements and procedures of the DHCA Healthcare Operators Regulation number (4) of 2013.
4.20	**Licensed Healthcare Professional:** a natural person engaged in a healthcare profession holding a License duly issued by the Licensing Board in accordance with the Healthcare Professionals Regulation and the applicable Rules, Standards and Policies.
4.21	**Licensed Pharmacy:** a healthcare facility holding a License issued by the Licensing Board in one of the categories stated in these standards to engage in the Practice of Pharmacy in accordance with the Healthcare Operators Regulation and the applicable Rules governing the Practice of Pharmacy.
4.22	**Medication:** Any prescription medications; sample medications; herbal remedies; vitamins; nutraceuticals; over-the-counter drugs; vaccines; diagnostic and contrast agents used on or administered to persons to diagnose, to treat, or to prevent disease or other abnormal conditions; radioactive medications; respiratory therapy treatments; parenteral nutrition; blood derivatives; and intravenous solutions (plain, with electrolytes and/or drugs).
4.23	**MOHAP:** Ministry of Health and Prevention.
4.24	**Non-Formulary Drug** means a drug not listed in the hospital formulary.
4.25	**OTC-P:** Over the counter pharmacy medicines
4.26	**Pharmacist-In-Charge:** Licensed Pharmacist designated and approved by the Medical Director as able to carry out the required roles and responsibilities.
4.27	**Product:** a drug or medication that may be dispensed by a Licensed Pharmacist to an individual to or for the benefit of such individual or their dependent.
4.28	**POM:** Prescription only medicines
4.29	**PH-OM:** Medicines restricted to Pharmacist Only
4.30	**Regulation:** any regulation approved by the Chairperson under the Law, including any amendments to any such regulation.
4.31	**Room Temperature** means temperatures between the range 15 - 30 ºC.
4.32	**Refrigerator temperature:** Temperatures kept between the range 2 – 8 ºC.
4.33	**Sterile Product**: a preparation that has undergone a valid sterilization process and is devoid of all living microorganisms, packaged in such a way to ensure the retention of this characteristic.

STANDARD – PHARMACY STANDARDS

5 REFERENCE	
5.1	DHCC Governing Regulation No. 1 of 2013
5.2	Healthcare Operators Regulation No. 4 of 2013
5.3	UAE FEDERAL LAW NO: 4, 1983 (The Pharmaceutical Professions and Institutions).