



Quality Oversight, Infrastructure and Accreditation of Pharmacies- Policy and Procedure

Appendix 1

PHARMACY QUALITY STANDARDS				
Pharmacy Name:		MOH License Number:		
Surveyor Name:		Date of Survey:		
Name of Attended Pharmacist:				
Assessment Outcome				
Staff Qualifications Education and Training				
Standards and Standards requirements	Yes	No	N/A	Remarks
Skills, duties and responsibilities for each position in the Health Organization are defined				
a) *All staff has a current, signed job description that defines and documents their assigned roles and responsibilities.				
b) *Assigned roles and responsibilities are consistent with background and training				
c) *Staffing levels and appointing qualified personnel are in accordance with local regulatory requirements				
d) *Students who are trained at the Licensed Retail Pharmacy are approved by MOH and consistent with MOH requirements				
Staffing meet regulatory requirements				
a) *Minimum one Licensed Pharmacist is present during the operational hours of the pharmacy				
b) *A ratio (1:3) of at least one Licensed Pharmacist per three Pharmacy Technicians is maintained, if pharmacy technicians are available				
Staff are available to assist patients upon arrival, and throughout the duration of the visit				
a) *A staff member is available to the patient upon arrival				
b) *All pharmacists and other pharmacy staff are wearing identification tags with titles				
The health organization maintains a current personnel file for each employee				
a) *Credentialing records are maintained for each pharmacist and pharmacist assistant.				



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b) *Records of ongoing internal and external education and training are maintained in each staff member's personnel files				
c) *All staff have a documented performance evaluation at least annually and a copy is kept in their personnel file				
OPERATIONS				
Standards and Standards requirements	Yes	No	N/A	Remarks
The facility has a process that helps patients to locate and identify the facility with ease				
a) Signs state hours of operation				
b) Signs are clearly visible				
c) Signs address cultural considerations, are multilingual, or use universally recognized symbols				
d) The Licensed Retail Pharmacy provides "after hours services" through voice mail direction, or referring to another Retail Pharmacy				
e) The certificate of registration is prominently displayed in the licensed pharmacy				
PATIENTS MANAGEMENT				
Standards and Standards requirements	Yes	No	N/A	Remarks
*The Health Organization is licensed to dispense medications *				
a) *The organization is licensed to dispense medications				
b) *The organization defines licensed personnel who can dispense medication				
c) *Sufficient medicines and chemicals to fill, compound or dispense all prescriptions are maintained				
d) *All medicines and healthcare products offered for sale are being approved for sale in the UAE by the MOH				
e) *All medicines are clearly marked with the latest MOH approved retail price				
All pharmacy prescriptions meet local requirements				
a) *Prescription medicines shall only be sold in accordance with prescription written within the previous six months by a UAE licensed doctor				



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b) *All prescriptions/ prescription orders used for dispensing product meet requirements listed in the DHCC Retail Pharmacy Rules				
c) *A Licensed Pharmacist is not authorized to make any changes to a prescription without prior approval of Prescribing Professional				
d) *Any approved changes or clarifications will be noted on the original prescription, including the date, time and name of Licensed Pharmacist who apply the changes				
All changes on the pharmacy prescriptions should be approved by a Prescribing Professional ,documented and communicated				
a) *Licensed Pharmacists should contact the Prescribing Professional to obtain further clarification in case an error or omission is discovered in a prescription				
b) *Any approval changes of a prescription are communicated to the patient				
c) *A Licensed Pharmacist has the authority to refuse filling a prescription, if evidence revealed that the product to be dispensed might be harmful to the patient, not prescribed according to the product's approval use or the validity of the product is questionable				
All medications requiring a pharmacy prescription are stored in a restricted access area				
a) *Prescription medicines are not available for self-selection by customers				
Counseling should be conducted to ensure patient education				
a) *Counseling by a Licensed Pharmacist should include The name and description of the product				
b) *Counseling by a Licensed Pharmacist should include the route of administration, dosage, dosage form and duration of therapy				
c) *Counseling by a Licensed Pharmacist should include special instructions or precautions for the preparations, administration or use of the product by the patient				
d) *Counseling by a Licensed Pharmacist should include common and severe side effects, interactions and contraindications that may be				



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encountered, including their avoidance and action required if they occur				
e) *Counseling by a Licensed Pharmacist should include Proper product storage				
f) *Counseling by a Licensed Pharmacist should include prescription refill information				
g) *Counseling by a Licensed Pharmacist should include Description of actions that should be taken in the event of a missed dose				
RECORD KEEPING				
Standards and Standards requirements	Yes	No	N/A	Remarks
Licensed retail pharmacy should maintain a database on patient information				
a) The Licensed Retail Pharmacy has a database for obtaining and maintaining patient information.				
b) The Patients database includes the following information: name and telephone number				
c) The database should include Individual history where significant				
d) The database should include known patient's allergies and drug reactions				
Narcotic and/or controlled drugs data base are attended according to federal procedures, rules and regulations				
a) The licensed Retail Pharmacy has data base that comply with the MOH requirement for controlled drug record keeping requirements				
Records of the licensed retail pharmacy are maintained				
a) The licensed retail pharmacy keeps record of medicines dispensed				
b) Records of purchases from different suppliers are available.				
STORAGE & FACILITY				
Standards and Standards requirements	Yes	No	N/A	Remarks
The facility ensures appropriate pharmaceutical storage				
a) *Products are stored in accordance with manufacturer recommendations with respect to temperature, light, ventilation, humidity and expiry dates.				



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b) *Proper air conditioning must be available to keep the temperature inside the Pharmacy at 20c° - 23 c° and humidity below 60%				
c) *Products and supplies are not stored on the floor. Products are stored at least 10 cm above floor level and 40 cm below the ceiling on shelving and in appropriate containers				
d) *Products should not be stored in cardboard shipping cartons				
e) *Flammable or hazardous products are stored separately, in appropriate containers/ Cabinet and away from the public				
The facility has a process to manage expired, unusable, rejected or recalled products				
a) *Expired, unusable, rejected or recalled products are removed and stored in containers labeled "Expired Items/Not for Sale"				
b) *The container for expired, unusable, rejected or recalled products is stored separately in a designated and dedicated lockable cupboard that is distinct from current inventory and secured from public access				
The facility ensures appropriate pharmaceutical storage of products requiring refrigeration				
a) *Refrigerators store only products recommended for refrigeration by manufacturer				
b) *Refrigerators are maintained at a temperature of between two (2) and eight (8) degree Celsius or as per manufacturer recommendation.				
c) *A digital or mercury free thermometer and a Temperature Log are physically presented.				
d) *The temperature is checked at a minimum twice a day and documented in the log. Constant temperature monitoring devices are recommended				
The facility ensures having an alarm system				



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a) There is an alarm installed in the fridge in case of power shut down to inform the security after working hour				
b) Refrigerators used for product storage have audible or remote alarm systems				
Environment of stored products is appropriate				
a) The licensed retail pharmacy floors shall be made of easily washable material				
b) The licensed retail pharmacy's facilities are maintained and kept in a clean and sanitary condition				
SECURITY REQUIREMENTS				
Standards and Standards requirements	Yes	No	N/A	Remarks
The facility ensures having a security system				
a) *The pharmacy installs and maintains windows and doors that are equipped with secure locks				
b) *A security system is maintained in the pharmacy to be utilized for emergency and "after hours services" or anytime the pharmacy is closed				
EQUIPMENT AND SUPPLIES				
Standards and Standards requirements	Yes	No	N/A	Remarks
Electrical and mechanical medical equipment meet current industry standards and undergo scheduled servicing, maintenance, and cleaning				
a) *Minimum required equipment and supplies are maintained by the pharmacy				
b) *Warranties, service agreements or other formal arrangements that ensure ongoing servicing and maintenance of medical equipment are current and available				
c) *Equipment maintenance is performed according to manufacturer's guidelines including calibration and validation to ensure good working order and is fully documented in detailed service reports				
d) *Records documenting the maintenance of the equipment and supplies are created and retained for a minimum of three years				
e) *A written preventive maintenance program for all equipment and related procedures are maintained by the pharmacy				
The facility manages stock in an appropriate manner				



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a) *The shelf-life of stock is long enough to cover a reasonable period of use				
b) *Stock rotation is conducted to ensure existing stock is sold before new stock				
c) *Weekly checks of expiry dates are done and logs are maintained and made available for record-keeping purposes				

QUALITY MANAGEMENT

Standards and Standards requirements	Yes	No	N/A	Remarks
The Health Organization has a process for reporting and managing incidents and near misses				
a) Standardized incident reporting forms are used to report incidents				
b) The Licensed Retail Pharmacy has a process in place for using information gained as a result of prescription error analysis as part of its quality improvement program				

The Health Organization has a process for managing complaints

a) The Licensed Retail Pharmacy has a mechanism and policy to systematically obtain feedback/ complaints from patients				
b) Patient feedback and complaints are documented				
c) The Licensed Retail Pharmacy has a process for utilizing patient's complaints so as to make improvements				

ENVIRONMENTAL MANAGEMENT AND INFECTION CONTROL

Standards and Standards requirements	Yes	No	N/A	Remarks
The Health Organization has a policy on Environmental Management and Infection Control programs				
a) *The Licensed Retail Pharmacy has a policy and procedure regarding the use of glove, mask, hand washing and disinfecting procedures				
b) *The Licensed Retail Pharmacy has a policy and procedure regarding environmental management				
c) *The Licensed Retail Pharmacy has a policy and procedure regarding the proper waste management				

LIBRARY

Standards and Standards requirements	Yes	No	N/A	Remarks
The Health Organization has minimum reference documents				



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a) *The Licensed Retail Pharmacy has the current edition reference books in either hard copy or soft copy				
b) *The licensed retail pharmacy has copies of local laws and MOH Narcotic and Controlled Policies and Procedures				
c) *Reports, circulars, policies and standards from the relevant regulators should be available on file for reference				

POLICIES AND PROCEDURES

Standards and Standards requirements	Yes	No	N/A	Remarks
*The Health Organization has written policies and procedures on recordkeeping, patient management, medical emergency, and management of equipment *				
a) *The Licensed Retail Pharmacy has relevant policies and procedures that address recordkeeping				
b) *The Licensed Retail Pharmacy has policies and procedures that address patient management practice				
c) *The Licensed Retail Pharmacy has a policy and procedure that address medical emergency				
d) *The Licensed Retail Pharmacy has policies and procedures that address management of equipment				

The Health Organization has written policies and procedures on patients rights and responsibilities, quality control, annual review, and training

a) The Licensed Retail Pharmacy include policies and procedures address patients rights and responsibilities				
b) The Licensed Retail Pharmacy include policies and procedures that address quality control				
c) The policies and procedures include provision for annual review and revision as necessary				
d) The policies and procedures include provision of training of all staff of the Retail Pharmacy				

REQUIREMENTS SPECIFIC TO COMPOUNDING PHARMACIES

Standards and Standard Requirements	Yes	No	N/A	Remarks
* The Health Organization ensures that compounding is done appropriately*				



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a) *There is a process to ensure that only licensed, trained and competent pharmacist perform compounding				
b) *The Licensed Retail Pharmacy assesses and evaluates the microbiological environment monitoring of surface, air and environment on a regular basis				
The compounded materials must meet local and regulatory requirements				
a) *Compounded materials shall have the preparation date and the expiry date documented				
b) *Compounded materials should have the lot number assigned to the prepared product				
c) *Compounded materials must have names of ingredients or solutions used, including their respective concentrations, manufacturer name, lot numbers and manufacturer expiry Dates				
d) *Compounded materials must include identities of personnel who have prepared the Product and the Licensed Pharmacist who performed the final check.				
The health organization maintains policies and procedures manual for compounding				
a) Compounding Policy and Procedure Manual must include methodologies for the formulation and compounding of preparations				
b) Compounding Policy and Procedure Manual is developed by the pharmacy for facilities and equipments cleaning and calibration				
c) Compounding Policy and Procedure Manual is developed by the pharmacy for maintenance operations				
d) Compounding Policy and Procedure Manual is developed by the pharmacy for Standards operating procedures of the facility				
e) Appropriate policies related to venting and exhaust incase toxic compounds or fumes are present				
Health, Safety & Environment				
Standards and Standard Requirements	Yes	No	N/A	Remarks
The health organization complies with applicable health safety and environment regulations, rules and standards				
a) "No Smoking" signs are clearly visible and the policy is enforced				



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b) The pharmacy implements a pest control program according local regulatory requirements				
The health organization ensures that there's a process for providing first aid				
a) Identified staff members are responsible for providing first aid				
b) First aid kits are visible, labeled, regularly checked and maintained by responsible staff members				
Electrical safety is maintained at all times within the facility				
a) *Electrical safety is maintained at all times and all electrical panels are clearly labeled				
b) *Defective cables, motors, or fans are not present in the facility				
c) *Multi-way adaptors are not used in the facility and power boards are not overloaded				
*The health organization is equipped with and maintains firefighting equipment and detection systems *				
a) *Firefighting equipment including smoke detectors are inspected, maintained and tested according to local regulatory requirements				
b) *Portable fire extinguishers are appropriately located and maintained				
c) *The pharmacy has an emergency evacuation plan aligned with local regulatory requirements and is clearly displayed, including emergency contact numbers				
d) *An identified staff member is trained and certified as the fire warden and is responsible for emergency evacuation				
e) *Emergency exits are clearly indicated and the exit routes are unobstructed				
f) *There is documented evidence that staff are trained on their roles and responsibilities during emergency evacuation and evacuation drills are conducted according to local regulatory requirements				