Pharmacy and Pharmaceutical Facilities Standards

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Introduction

Objectives of Licensing

Licensing is a statutory mechanism in the Kingdom of Bahrain which grants permission to health care organizations and/or facilities to operate and deliver health care services. A fundamental role of the NHRA is to ensure that health care organizations / facilities meet minimum standards to protect public health and patient safety and ensure health care services are of a high quality.

The NHRA grants Health Care facilities a license on an annual basis. This time limited approach requires that the facility not only complies with the minimum standards to operate at the outset, but also maintains the standards over a sustained period of time to ensure re-licensure is achieved.

License Inspection Surveys

Each inspection survey is carried out using an open and transparent process whilst applying the standards within the facility.

The inspectors will work in a facilitative manner and will discuss and consider specific areas of individual elements of the standards throughout the onsite inspection process.

Standard Development

The NHRA licensing standards have been developed using a consensus process. During the development the standards went through reviews by various stakeholders, recommendations for change were reviewed, considered and applied where appropriate. The standards have been piloted across a number of Pharmacy facilities already operating throughout the Kingdom to ensure applicability before being approved by the NHRA Board.

The Licensing Standards Structure

The NHRA Pharmacy/Pharmaceutical Facilities Licensing Standards are assembled around key services and functions

Core Elements – (applicable to all Pharmacy Facilities)

All Pharmacy facilities are assessed against all core elements of the standard

Each element has an introduction which provides an explanation about the relevance and contribution to safety and high quality patient care. Each element has a statement and when required sub-standard elements are identified to clarify further requirements. Each element has identified Evidence of Compliance (EoC).

1. Governance, Management and Leadership
2. Human Resources
3. Patient and Family Rights
4. Quality and Safety
5. Management of Information and Pharmacy Records
6. Pharmacy Premises and Equipment
7. Medication Storage and Stock

Support Element

8. Warehouse Procurement
9. Distribution and Storage

Element One – Governance, Management and Leadership

Introduction

For any Pharmacy, quality and patient safety depend on effective leadership and good organization.

It is important for all pharmacy facilities to have a clearly stated objectives and a mission. It is the responsibility of the leadership of the facility to develop the objectives and mission and provide adequate resources to fulfill these.

Element 1: Governance, Management and Leadership Minimum Criteria

Governance elements **1.1 to 1.3** apply to pharmacies or chain of pharmacies that have a governing body in place:

1.1. The governing body responsibilities are defined in written documents such as bylaws, policies and procedures and reflect the legal responsibilities and accountability it has to the patients and public.

EoC: Governance responsibilities and accountabilities are described in documents. This should include responsibility for the quality of care provided and patients' safety.

1.2. The governing body fosters communication and coordination between the pharmacy facilities governance function and management within the pharmacy.

EoC: There is evidence of communication and coordination between the pharmacy governance function and management. The governance body approves the mission statement, scope of services, strategic and management plans implemented through the management and leadership function.

1.3. The governing body performs periodic evaluation on both its own effectiveness and that of the leadership and management team, including review of plans, budgets, policies and procedures.

EoC: There is evidence of periodic evaluation of the governing body effectiveness and that of the management and leadership function within the facility which includes plans, budget, policies and procedures.

1.4. The pharmacy leadership and management ensure that it complies with the laws and Regulations in the Kingdom of Bahrain.

EoC: The pharmacy has a current NHRA License and adheres to the current Kingdom of Bahrain laws.

1.5. The management structure is defined with a clear, current organizational and accountability chart identifying name/s and line/s of authority and responsibility of those leading, including the governing board /person(s) where appropriate.

EoC: The governing structure is defined, updated, and circulated throughout the pharmacy: It shows the names and titles of those responsible for management and leadership, clear lines of authority and accountability.

1.6. The pharmacy facility should have a clear mission statement which is regularly reviewed and is communicated to all staff, patients and visitors.

EoC: There is a written mission statement publicly posted within the pharmacy and staffs are aware of the mission statement.

1.7. The pharmacy should have a documented scope of services and practices provided.

EoC: The pharmacy has an approved and documented scope of services and practices provided including the dispensing prescribed drugs, controlled drugs, OTC drugs, Advice and Education, counseling, provision of health foods services etc.

1.8. The pharmacy should have a strategy for providing the identified scope of services/practices which includes the provision of adequate resources (manpower, consumables, and capital assets).

EoC: Adequate resources are available for the pharmacy to provide the approved scope of services, including adequate manpower, adequate consumables, adequate equipment and adequate contracted services where required.

1.9. A full-time person should be assigned to manage the pharmacy in accordance with applicable laws and regulations. They should have a clear written job description covering all aspects of their role.

EoC: An appropriately qualified person is appointed and in post as the person who is held accountable for overall pharmacy management and there is evidence of his/her performance being managed.

1.10. The pharmacy fosters open and transparent communication and coordination between its management and leaders and the staff.

EoC: There is evidence of communication between management and staff through newsletters, meetings, training and education, notice boards, staff initiatives etc.

1.11. The pharmacy promotes a top down and bottom up approach to performance improvement, patient safety, and a risk management program by collating, regularly reviewing and acting upon reports and trends.

EoC: There are systems in place for collating performance improvement, patients' safety and risk management statistics and information. There is evidence that this information is regular reported and reviewed including:

- **Performance improvement activity**
- **Patient safety initiatives**
- **Risk management activities**
- **Trending reports and actions taken**

1.12. The pharmacy owner/leaders are aware of the current and future demands for their service within the community and plan services accordingly. Planning includes engaging with staff, patients and community.

EoC: There is evidence that the pharmacy owner/leadership collaborate with community and other stakeholders including patients to plan services required within the community.

1.13. The pharmacy leaders use evidence and best practice information to develop and improve services.

EoC: The leaders while designing and improving services use and encourage staff to use evidence and best practice information.

1.14. The facility can provide annual reporting information regarding:

1.14.1 The range of services provided

1.14.2 The age groups of patients attending.

1.14.3 The number of patients seen annually.

1.14.4 Number of complaints received

1.14.5 Number of incidents occurred

EoC: Annual reporting information is available for elements 1.14.1 to 1.14.5

1.15. There is a written policy for controlling the development and maintenance of policies and procedures for key functions and processes, Policy development should include:

1.15.1 A unique identification for each policy with title, number, and dates of issue and updates.

1.15.2 Policies being developed, approved, revised, and terminated by authorized individuals.

1.15.3 Policies being revised according to a defined revision due date that does not exceed (2) years or when required.

1.15.4 All Policies are dated and current.

1.15.5 Policies being communicated to staff and training provided where applicable.

1.15.6 Staff sign off on polices being implemented, ensuring staff understand their role in implementation.

EoC: There is a policy on policies and procedures, how the policies are developed, approved, revised, tracked, communicated, monitored and terminated.

1.16. There is staff understanding on the policy on policies and procedures

1.17. There is oversight regarding all external contracts for clinical or operational services, ensuring the services to be provided are clearly identified and the services meet the applicable laws and regulations and are consistent with the standards required.

EoC: There is evidence of a contract oversight process which ensures that services to be provided are clearly identified and they are provided in a way that is consistent with the standards required for regulation and licensing.

1.18. The pharmacy management and leadership have basic knowledge of quality management concepts which includes:

1.17.1 How to analyze data.

1.17.2 How to use an improvement cycle (e.g., PDSA or another model) to make improvements.

1.17.3 How to work using work flow processes.

EoC: There is evidence of leadership involvement and educational programs on quality management concepts, data analysis, PDCA, RCA and team work.

Element Two -Human Resources

Introduction

All pharmacies must have qualified staff with the right amount and mix to meet its purpose. The roles and responsibilities of each staff must be clearly defined in a current job description. Staff must be oriented to the pharmacy facility, their department, and job. Their knowledge, skills, and abilities must be continually upgraded and their performance assessed regularly. An ongoing education program must be in place. Additionally, when gaps in knowledge, skills, or abilities are identified the staff must receive appropriate training. A current, updated personnel file must exist for each employee and should contain all relevant personal details.

Element 2 -Human Resources Standards - Minimum Criteria

2.1 The pharmacy facility maintains a personnel file for each employee, which is complete, up to date and maintained in a confidential manner.

EoC: There is a personnel file for each employee and there is a written policy which is implemented for maintaining confidentiality.

2.2 All new employees receive a comprehensive induction and orientation program which includes but is not, limited to:

2.2.1 The pharmacy mission and organizational chart.

2.2.2 Staff role in disasters and emergencies. (i.e., Fire, evacuation)

2.2.3 General information about hazardous materials including Material Safety Data Sheets (MSDS)

2.2.4 General information on standard infection control measures and sharps disposal.

2.2.5 Electrical safety.

2.2.6 General information on communication: paging, telephone system, fax, filing, record keeping etc.

2.2.7 General information on staff performance evaluation processes.

2.2.8 The definition of Incidents, adverse events and near miss events along with the process of reporting including Who should report, When to report, How to report, and to Whom the report is routed.

2.2.9 Information on dealing with patient complaints

2.2.10 General information about the quality improvement and patient safety processes of the pharmacy facility and the importance of involvement of every member of staff.

2.2.11 Information on the expected ethical conduct of the staff and the expected professional communication in his/her interactions with others.

2.2.12 Information on protection of patients' rights, privacy and confidentiality.

2.2.13 All policies are provided and are signed that they have been read and understood.

EoC: Attendance records show that all new employees attended a mandatory general orientation and are documented in each employees personnel file. The orientation includes points 2.2.1 to 2.1.13 and is documented and signed off in the individuals personnel file.

2.3 The pharmacy has a policy that addresses methods for dealing with staff complaints and managing resolution of conflicts between staff.

EoC: The pharmacy has a policy for handling staff complaints and staffs are aware of this policy.

2.4 All staff positions in the pharmacy have a clearly written job description that is reviewed and revised at least every (3) years and as needed and:

2.4.1 Is used when selecting employees for hire, internal promotions, and transfer.

2.4.2 Outlines the necessary knowledge, skills, and attitude to perform the role.

2.4.3 Is provided to every employee on hiring and is located in every employees personnel file.

EoC: There is a job description policy which ensures all job descriptions follow a described format that outlines the necessary knowledge, skills and attitude required to perform the role and is reviewed every three years. All staff has a copy of their job description.

2.5 Staff are educated and trained on the safe operation of equipment, including medical devices, and there is a clear process to ensure that only trained and competent staff operates specialized equipment.

EoC: There is evidence of staff education on the safe operation of equipment together with tools to ensure competency of staff.

2.6 All staff members who have received training in basic cardiopulmonary resuscitation, updated as required.

EoC: The basic cardiopulmonary resuscitation training for staff members who have direct contact with the patient is valid and repeated every 2 years.

2.7 The pharmacy has processes in place to address the health and safety of staff: based on assessment, and where necessary, reduction of occupational health and safety risks. The facility has an employee health program which includes, but is not limited to:

2.7.1 Pre-employment medical evaluation of new employees including preventative immunizations.

2.7.2 Measures to reduce occupational exposures and hazards, including use of protective equipment and clothing, stress management, and ergonomic positioning.

2.7.3 Staff education on the risks within the environment as well as on their specific job-related hazards, e.g., lifting techniques, using equipment safely, and detecting, assessing, and reporting risks. Management and documentation of staff incidents, e.g., injuries or illnesses, taking corrective actions, setting measures in place to prevent recurrences.

EoC: The facility has policies which address points 2.7.1 to 2.7.3 in the standard. All issues related to staff medical fitness and wellness are documented in their personnel file.

2.8 The facility ensures that all healthcare professionals (full time, part time, locum, etc.) are licensed with the Kingdom of Bahrain NHRA, and maintains a register of the current professional licenses.

EoC: There is evidence that all professional staff are currently licensed to work in the Kingdom of Bahrain.

Element 3 - Patient and Family Rights

Introduction

Every client is unique with his/her own needs, values and spiritual beliefs. In alignment with these issues, the pharmacy facility is responsible for ensuring that patient and family rights are defined and respected within the facility.

There is a need to establish confidence, trust and clear communication with clients and to understand and protect each person's cultural, psychosocial and spiritual beliefs.

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Element 3 -Patient and Family Rights – Minimum Criteria

3.1 The pharmacy facility supports and protects patient and family rights by:

3.1.1 Developing and maintaining a Patient Rights and Responsibilities statement and policy to outline and support patient rights. These should include aspects such as:

3.1.1.1 Treating patient with respect and dignity at all times.

3.1.1.2 Respecting patients' cultural, psychosocial, spiritual and personal values and beliefs.

3.1.1.3 Providing all the information regarding the identity and the professional status of his/her pharmacist.

3.1.1.4 Respecting the patients' need for privacy

3.1.1.5 Ensuring complete patient confidentiality by never discussing the patient in public, never revealing the patient name or any information about them, and not publicizing any information.

3.1.1.6 Not neglecting patients' demands and/or needs, and respecting their right to complain.

3.1.1.7 Allowing patients to submit verbal or written complaints or proposals with no effect on the quality of care provided.

3.1.1.8 Protecting patients from verbal abuse from any member of staff.

3.1.2 Ensuring patients are informed about their rights and responsibilities in a manner they can understand

3.1.3 Clarifying and helping resolve issues that involve patient's rights.

3.1.4 Making patient rights and responsibilities available to patients and families.

3.1.5 Providing staff training and education on patient and family rights and responsibilities.

EoC:There is a written patient's rights and responsibility statement and policy that include identified areas. Staff and patients are aware of the statement and policy in place. There is evidence of patients' rights being discussed at senior management level and staff receives training on this area.

3.2 An administrative policy is developed and implemented regarding everyone's roles and responsibilities in supporting patient and family rights

EoC: There is an administrative policy that outlines staff roles and responsibilities in implementing patient and family rights.

3.3 The facility offers equal treatment to patients and they know the estimated cost of any drugs/treatment in advance.

EoC: There are standardised processes for patient care and treatments. Cost of drugs/treatment is published and displayed for all patients.

3.4 The facility assists disabled patients by offering the necessary assistance to patients with special needs where needed (e.g. identified parking spaces near the entrance)

EoC: The facility is friendly for disabled and elderly patients (e.g. parking spaces near the entrance, ramps where necessary)

3.5 The pharmacy facility has an effective structure to handle complaints and can show satisfactory resolution for the complainant.

EoC: There is a designated person within the facility who is responsible for complaint management. There is a complaint management policy that is implemented and there is oversight of the patient complaint process and outcomes.

3.6 All complaints are trended, aggregated and analysed on a quarterly basis and a summary report is presented to the management and leaders in the facility for discussion and action as appropriate.

EoC: There are trended reports concerning complaints which allow the facility to identify problem areas for improvement.

3.7 The facility has a system including policy, forms and process to conduct on-going satisfaction surveys and makes improvements based on the trended survey results.

EoC: There is a policy and form for on-going satisfaction survey which is trended and provides reports for improvement actions to be taken.

3.8 The facility adopts an ethical approach to advertising and marketing, honestly portraying its services to patients.

EoC: The facility has a code of ethics and markets its services honestly.

Element 4 - Quality Management and Safety

Introduction

A pharmacy should operate a structured error handling system which ensures that when an adverse event occurs, the safety of the patient is the primary focus and learning from the incident occurs to prevent or reduce the risk of re-occurrence.

It should have a policy, which requires evaluation and ongoing amendment, of systems to prevent and/or minimise the risk of error in the management and supply of medicines and information. Any adverse incident occurring in a pharmacy should be dealt with promptly, efficiently and professionally and should always ensure that the welfare and safety of the patient is the primary focus.

Element 4 – Quality Management and Patient Safety - Minimum Criteria

4.1 There is a person identified who coordinates and leads quality concepts and principles within the pharmacy facility.

EoC: There is a named person within the pharmacy who coordinates and leads quality concepts and principles.

4.2 The pharmacy facility develops and implements a quality improvement and risk management plan that is systematic, continuous, facility-wide, supports innovation, and covers all aspects of performance. The plan should include, but is not limited to, the following:

4.2.1 Scope and objectives of the plan.

4.2.2 Staff responsible for the plan.

4.2.3 A systematic process to identify and analyse potential risks for severity and likelihood of occurrence

4.2.4 Development of interventions to manage potential risks/hazards/incidents (e.g., reduction, prevention).

4.2.5 Documentation of risk management and quality improvement activities.

4.2.6 Staff education on their roles and responsibilities related to the plans.

4.2.7 Describing the criteria used for selection of indicators, collection of data, data analysis, and implementation and evaluation of improvements.

4.2.8 Identifying monitoring indicators (including temperature/humidity controls, expiry date checking, controlled drug usage, adverse reactions, counterfeit drugs etc.

4.2.9 Regular review of the plans to ensure that the plans are effective:

EoC: There is evidence that the pharmacy staff use a planned approach to identify, analyse potential risk/near miss processes and implement interventions to eliminate or minimise the potential risks.

4.3 Quality Improvement is considered in staff meetings, either as a standalone concept or within the team meetings.

EoC: There is evidence that the staff participate in quality improvement discussions and implement actions identified from discussions. There should be minutes available for inspection.

4.4 The pharmacy facility has an incident (occurrence/variance/accident) reporting system (policy and form) that staff follows and use when reporting errors, adverse events and near misses.

4.4.1 Reportable incidents, errors and near misses are identified.

4.4.2 An identified staff member is responsible for managing the incident reporting system.

4.4.3 All Errors/incidents/near misses are reported, investigated and addressed promptly, efficiently and professionally.

4.4.4 Immediate actions are taken as well as identifying learning outcomes for action to prevent recurrence.

4.4.5 Patients are informed when involved in incidents with documentation errors etc.

4.4.6 Incidents are monitored over time and trended information is used for improvements.

4.4.7 All staff are educated on the incident reporting system used within the facility.

EoC: The pharmacy facility has a policy, forms, and process in place for reporting incidents and near misses. Aggregated incident reports can be produced to show trending of incidents and near misses.

4.5 The pharmacy facility adopts a checking process for all medications being dispensed and a process that requires a qualified pharmacist and preferably one other to check whenever dispensing controlled medications.

EoC: The pharmacy facility has a policy for ensuring prescriptions are double checked before dispensing and that a qualified pharmacist and preferably one other check whenever dispensing controlled medications.

4.6 The pharmacy facility has a process for the safe storage and handling of all medications, medicated creams, IV fluids and other medicinal preparations.

EoC: There is a policy and process for the safe storage and handling of all medications, medicated creams, IV fluids and other medicinal preparations.

4.7 The pharmacy facility develops and implements a set of indicators that are collected and aggregated on a regular basis and are used for quality improvement as well as strategic and operational planning. These may include:

4.7.1 Staff satisfaction.

4.7.2 Customer satisfaction

4.7.3 Adverse effects / reactions

4.7.4 Near miss events.

4.7.5 Patient complaints.

4.7.6 Medication errors.

EoC: Quality indicators as suggested are identified and set by the leaders in the facility. These indicators are monitored and reviewed to inform quality improvement activity.

Element 5 - Management of Information and Pharmacy Records

Introduction - Management of Information

A pharmacy must recognize the importance of data management and provide for the associated responsibilities. Suitable procedures must be provided that make due provision for the safe management of personal patient information, and allow for records to be maintained that are compliant and satisfy all legal and ethical responsibilities.

One of the most valuable resources for any facility is information. Accurate information is necessary to support decision making. Information that is trended over time can be evaluated to see if any improvements need to be made or to evaluate the effectiveness of an improvement that has been done. The ambulatory care facility should have a process to meet the information needs of its clinical and managerial leaders and to compare its performance with other databases when relevant.

Among the main requirements of this function are:

- Information needs assessment
- Information planning
- Data collection and analysis
- Information flow and reporting requirements
- Security, integrity, and confidentiality

Introduction - Pharmacy Records

Pharmacy Records are considered one of the important elements in a quality program. The quality of all records is essential. To ensure appropriate management of pharmacy records, the facility should have processes for recording ordering/delivery of medications, expiry date recording, dispensing records, error and incident management records, controlled drugs records, and .

Element 5 Management of Information- minimum standards

5.1 The pharmacy facility develops and implements information management policy and processes to meet the information needs for those who manage the facility and adheres to all legislative requirements, this should include:

5.1.1 A definition of data, information, security, confidentiality and integrity.

5.1.2 A categorization of data available (both manual and electronic)

5.1.3 A description of how confidentiality, security, and integrity of the data and information will be maintained.

5.1.4 A description of the various kinds of reports, the frequency of the reports, and who will receive them.

5.1.5 An educational/training schedule for decision makers and other appropriate staff on the principles of data management for decision-making.

5.1.6 A description of the roles and responsibilities of the leadership and department heads in relation to implementation and evaluation.

EoC: There are comprehensive information management processes developed by the leadership including 5.1.1 to 5.1.6.

5.2 The pharmacy facility should determine the roles and responsibilities for data entry (completion of forms), data collection, data analysis, and reports generation and this includes:

5.2.1 Data elements being defined and forms developed for designated staff to enter the necessary data.

5.2.2 Establishing time frames for collecting data.

5.2.3 Displaying and analysing data

5.2.4 The leadership deciding reporting requirements and ensuring they are implemented. e.g. Controlled drug usage, adverse reaction reports, near miss/incident reports.

EoC: There is policy and process for all data recording and management; this includes data elements being defined and process for collation being defined.

5.3 When there is automation of data, there is a planned, documented recovery system in case of computer malfunction to include system linked and standalone computers.

EoC: There is documented recovery system for automated data on all computers.

5.4 The pharmacy has a process in place that facilitate controlled access to pharmacy records and confidential information. this should also include a secure method for disposing of obsolete confidential information

EoC: Files and pharmacy records are stored in a secure locked area with access to authorised individuals only.

5.6 The pharmacy has an appropriate filing system used for all prescriptions dispensed at the facility. The process /system should

5.6.1 Facilitate prompt retrieval of each and every prescription dispensed and retained at the pharmacy

5.6.2 Provide a system for filing repeat prescriptions that are retrievable when subsequent dispensing occurs

5.6.3 Facilitate a mechanism for reviewing repeat prescription files for regular removal and updating to minimise the risk of inappropriate prescribing and dispensing.

EoC: There is evidence that the pharmacy has an appropriate filing system that facilitates easy retrieval and checking of any/all prescriptions dispensed in the pharmacy.

5.7 All dispensed controlled drug prescriptions should be retained for five years after the date of dispensing in accordance with Bahraini law.

EoC: there is evidence of all prescriptions being retained in an orderly and secure way that is accordance with the requirements in Bahraini law.

5.8 All prescriptions should be annotated and/or endorsed at time of dispensing

EoC: All prescriptions are annotated /endorsed as being dispensed at the time of dispensing.

5.9 The Controlled Drugs register should be maintained in the form of a bound book with one preparation per page and in accordance with relevant legislation. It should be

5.9.1 Up to date and accurately reflect the content of the controlled drugs cupboard

5.9.2 Legible, with all entries clear and written correctly

5.9.3 Retained on the pharmacy premises for two years after the date of the last entry.

EoC: There is evidence that a controlled Drugs book is used, maintained and has the correct balance/ running total for each controlled drug being held in stock.

5.10 Prescription labels should be clear and legible and contain:

5.10.1 Date of dispensing

5.10.2 The name of the patient

5.10.3 The name and address of the pharmacy who supplied the preparation

5.10.4 The proprietary name of the preparation or the generic name with the name of the producer.

5.10.5 Directions for use and any precautions specified on the prescription

5.10.6 Any required cautionary or warning notices relating to the preparation

5.10.7 The words “keep out of reach of children”

5.10.8 If for external use only, the words “for external use only”

EoC: The prescription labels and clear and legible and contain the information required in 5.10.1 to 5.10.8

5.11 The pharmacy should have recorded systems and processes for recording

5.11.1 Non compliance

5.11.2 Side effects/adverse reactions/interactions

5.11.3 Drug regime changes

EoC: there is evidence that the pharmacy has processes and systems which facilitate recording and trending of 5.11.1 to 5.11.3.

Element 6 – Pharmacy Premises and Equipment

Introduction

All aspects of a pharmacy premises should be well maintained, it should enable and facilitate a safe and effective working environment.

All equipment should be located, adapted and maintained to suit the professional operations carried out in the pharmacy environment.

Element 6 – Pharmacy Premises – Minimum Criteria

6.1 All aspects of the pharmacy should be well maintained and facilitate a safe working environment, with the professional services area identifiable to the patient, which include but limited to:

6.1.1 Suitable wall, floor and ceiling coverings.

6.1.2 Security system in place

6.1.3 Areas for authorised personnel only

6.1.4 Routine maintenance schedules adhered to.

6.1.5 Fire alarm and exits maintained

6.1.6 No smoking environment

EoC: There is evidence that the facilities are maintained to facilitate a safe working environment that includes as a minimum 6.1.1 to 6.1.6. The dispensary area/professional services area is easily identifiable for the customer.

6.2 Staff changing, rest room, toilet and hand-wash facilities should be provided and should not open directly into the dispensary. All staff should use these facilities to

6.2.1 Eat or drink away from the dispensing area,

6.2.2 Wash their hands, A 'Wash your hands' notice should be displayed.

EoC: There is evidence that staff have changing, rest, toilet and hand washing facilities. Staff has an area that they can eat or drink away from the dispensing area and use hand washing facilities when required.

6.3 The pharmacy should be maintained in a clean and good working condition. Appropriate cleaning schedules should be detailed and recorded. Adequate heating, lighting, ventilation and air conditioning should be provided and maintained.

EoC: There is evidence that the pharmacy is cleaned and maintained regularly. There are cleaning schedules available for inspection. There is evidence that adequate heating, lighting, ventilation and air conditioning is provided and maintenance schedules are available for inspection.

6.4 Temperature and humidity conditions should be controlled and monitored with due regard to the requirements to store pharmaceutical products within certain specified temperature parameters.

EoC: There are temperature and humidity recording carried out on an on-going basis and past/present recordings are available for inspection. There is evidence that drugs are maintained in the environment required as per manufacturer's instructions.

6.5 All signage on windows and doors should be kept to a minimum in accordance with relevant security guidance. Notices relating to opening hours, duty rotations, after hours' service, prices etc. should be factual and available for the public to see.

EoC: there is evidence of signage being kept to a minimum in the window. All notices are factual and are made available to the public.

6.6 The facility license and professional registration certificate of the supervising pharmacist responsible for the professional activity of the pharmacy should be on public display.

EoC: The facility license and the registration of the pharmacist in charge is on display.

6.7 Medicine sales counters should not be cluttered. All pharmacy medicines should be located behind the counter so that the pharmacist is able to intervene personally in the supply of a medicinal product. The pharmacy should site hazardous products out of the reach of children.

EoC: All prescription medicines or those medicines that can be used to cause harm or abuse are kept behind the dispensing counter where the pharmacist can control the dispensing. All hazardous products are kept out of reach of children.

6.8 The pharmacy should provide a patient services area in which counselling can take place.

EoC: There is evidence of a quiet area available for the pharmacist to offer counselling services to the patient if required.

6.9 The physical environment and layout of the dispensary must be robust, hygienic and provide for the safe delivery of patient care and should:

6.9.1 Be a sufficient size to allow effective workflow and take account of practice-specific variables such as staffing, work-flow and prescription volume.

6.9.2 Have adequate means of storage and waste disposal.

6.9.3 Have a lockable drug cabinet for safe storage of controlled drugs. The keys should be kept solely by the pharmacist in charge.

6.9.4 Have a refrigerator that is cleaned and maintained regularly and temperature records maintained daily at intervals.

6.9.5 Have an approved fire extinguisher present, that staff are trained to use

EoC: The dispensary area meets the minimum requirements 6.9.1 to 6.9.5

6.10 The pharmacy facility should have appropriate and adequate dispensing equipment to carry out the operations of the pharmacy, which is adequately stored and maintained. This should include

6.10.1 Dispensing, measuring, weighing, recording and control equipment.

6.10.2 Adequate Labelling equipment, using electronic or mechanical printer systems.

6.10.3 A suitable means of counting tablets accurately.

6.10.4 All equipment should be regularly serviced, checked and calibrated, records maintained for inspection.

6.10.5 Dispensary equipment should be for the sole purpose of preparing and dispensing medicines.

6.10.6 A sink/wet area used for dispensing purposes only

EoC: There is equipment available in the dispensary as described in 6.10.1 to 6.10.16

Element 7 Medication Storage and Stock

Introduction

A pharmacy practice should operate a comprehensive, auditable system for the control and maintenance of an appropriate level of legitimate stock which is held within prescribed storage conditions and facilities.

Stock must be sourced from a licensed supplier to ensure that the requirements of safety, quality and efficacy are upheld and the risk of counterfeit stock entering the supply chain is eliminated.

Stock must be stored in appropriate and auditable environmental conditions. Appropriate conditions of light, humidity, ventilation, temperature and security should be ensured. All medicinal products must be stored in accordance with the manufacturer's directions and within the terms of product authorizations.

Element 7 Medication Storage and Stock - Minimum Criteria Standards

7.1 Appropriate control and operational policies and procedures should be in place to ensure the control, accessibility, receipt, storage and maintenance of stock. This should included:

7.1.1 Maintenance of cold chain and temperature mapping

7.1.2 Procedures when cold chain fails

7.1.3 Expiry date checking and follow up procedures

7.1.4 Ordering and Receiving medications and checking procedures

EoC: There is evidence of policies and procedures that are in place and implemented to ensure appropriate controls are adhered to. Including 7.1.1 to 7.1.4.

7.2 Stock must be sourced from a licensed supplier to ensure that the requirements of safety, quality and efficacy are upheld and the risk of counterfeit stock entering the supply chain is eliminated.

EoC: There is evidence that medication stock is sourced from licensed supplier through appropriate invoicing and receipts. Wholesale suppliers license is available on request.

7.3 Appropriate controls must be exercised internally to ensure appropriate receipt of goods and an appropriate accountability chain within each pharmacy. These controls should include written policies and procedures for

7.3.1 All medicines being retained in their original manufacturers packaging

7.3.2 Any damaged products received should be quarantined and returned to supplier

7.3.3 All drugs should have batch number and expiry dates recorded and a documented procedure in place for systematically checking expiry dates

7.3.4 Medicines must not be removed from blister or foil packs

7.3.5 Care should be taken when different medications are stored in similar packaging

7.3.6 All disposal of medications should be carried out in a manner consistent with the legal requirements

7.3.7 Any patient returned medications should not be re-dispensed and should be disposed of as soon as possible.

7.3.8 A medicine and product recall procedure should be developed, documented and regularly reviewed to ensure efficient response to recall notifications.

EoC: there is written policies and procedures that are adhered to and implemented to ensure the proper receipt of medications and the accountability chain is maintained. Elements 7.3.1 to 7.3.8 are included.

7.4 Stock must be stored in appropriate and auditable environmental conditions. Appropriate conditions of light, humidity, ventilation, temperature and security should be ensured. All medicinal products must be stored in accordance with the manufacturer's directions and within the terms of product authorisations

7.4.1 Environmental conditions, (temperature, humidity etc), in the pharmacy should be monitored and recorded twice daily using regularly calibrated equipment.

7.4.2 Medicines should not be stored in close proximity of where food and drink is stored, prepared or eaten.

7.4.3 Hazardous substances, including poisons should be kept separate from the main pharmacy stocks.

EoC: All medications should be stored in accordance with their manufacturer's instructions. There is evidence that environmental conditions are monitored on a daily and twice daily basis. Segrated areas are identified and 7.4.1 to 7.4.3 are considered.

7.5 There should be appropriate classification and retrievability of stock to ensure safe and efficient practice.

EoC: there is a written policy and procedure to ensure appropriate classification and retrievability of stock is implemented.

7.6 When a delivery is received by the pharmacy, the invoice and/or delivery note should be examined for the presence of:

7.6.1 Controlled drugs that need to be checked and removed immediately to the controlled drug cupboard

7.6.2 Any medications that require refrigeration. They must be checked and immediately taken to the refrigerator.

EoC: There is a policy and procedure for the delivery of medications that is implemented to ensure that the integrity of the medication is not compromised on during transport and arrival at the pharmacy.

7.7 Careful consideration is given to all OTC drugs, where there is potential for misuse, such as preparations including codeine, cough suppressants, slimming products, laxatives and paracetamol. These should be stored behind the counter.

EoC: All drugs with a potential for misuse are stored behind the counter.

7.8 All pharmacy waste should be handled and disposed of in a safe and effective manner that complies with the relevant legislation on this issue.

EoC: There is a contract in place with the medical waste contractor and there is evidence that medical waste is disposed of in a safe and effective manner. There is a written procedure which is implemented for the disposal/destruction of controlled drugs and other medicines.

Element 8 Warehouse Procurement and Storage -

Introduction

Patients are entitled to expect that medicines and health products sold from a Pharmacy and pharmaceutical facilities are fit for their intended purpose. Control of storage temperatures is essential in maintaining the quality of medicines and to protect patients from ineffective products that may result from inadequate control.

Pharmaceutical wholesale warehouse procurement and distributors are obliged to exercise control over the distribution chain to ensure that the quality of medicines is maintained up to delivery to the pharmacy

Element 8 Warehouse Procurement and Storage - Minimum Criteria Standards

8.1 All pharmaceutical products in the warehouse are licensed for use and distribution in the Kingdom of Bahrain

EoC: There is evidence that all pharmaceutical products stocked in the warehouse are licensed for use in Bahrain

8.2 The warehouse distribution centre must be licensed to operate in the Kingdom of Bahrain through the NHRA.

EoC: The warehouse distribution Centre has valid NHRA license to operate.

8.3 Stock must be sourced from a licensed manufacturer to ensure that the requirements of safety, quality and efficacy are upheld and the risk of counterfeit stock entering the supply chain is eliminated.

EoC: There is evidence that medication stock is sourced from licensed manufacturer through appropriate invoicing and receipts. Manufacturers and wholesale suppliers' licenses are available on request.

8.4 There should be evidence that the warehouse and distribution practices are in accordance with the Ministry of Health vaccine quality guidelines, where shipment, storage and transportation requirements are identified.

EoC: There is evidence that the warehouse adheres to the MoH guidance on the shipment, storage and transportation of all vaccines

8.5 Wholesale distributors must maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities. The system for managing quality should encompass as a minimum:

8.5.1 The organizational structure, procedures, processes and resources, as well as activities necessary to ensure confidence that the product is delivered safely. Examples of which are:

8.5.1.1 Expiry date checking and follow up procedures

8.5.1.2 Ordering and Receiving medications and checking procedures

8.5.1.3 A program of calibration of temperature measuring devices, particularly in cold chain storage areas.

8.5.1.4 Procedures for monitoring all storage facilities and areas

8.5.1.5 temperature mapping of storage area and vehicles

8.5.1.6 procedures when cold chain fails

8.5.1.7 transport arrangements are validated and monitored

8.5.1.8 there is a comprehensive staff training program including drivers

8.5.1.9 there is a technical agreement with couriers

8.5.1.10 there is a periodic audit and review of quality assurance activities

EoC: There is evidence of policies and procedures that are in place and implemented to ensure appropriate controls are adhered to. Including 8.5.1.1 to 8.5.1.10

8.6 Additional control and operational policies and procedures should be in place to ensure the control, accessibility, receipt, storage and maintenance of high risk stock, particular some cold chain products, such as:

8.6.1 vaccines, insulin, biotech products and those derived from blood or plasma, which are classified as high risk because they are at risk from freezing as well as from elevated temperatures.

EoC: There is evidence of policies and procedures that are in place and implemented to ensure appropriate controls are adhered to for high risk products as identified in .8.6.1.

8.7 Returned cold chain products cannot be considered for resale and must be immediately stored in a dedicated and marked area awaiting disposal.

EoC: there is evidence to show that a process is in place and implemented for the returned cold chain products that must not be submitted for resale and must return to the manufacturer.

8.8 Standard domestic refrigerators are not suitable for storing cold chain products. A purpose-built pharmaceutical refrigerator is recommended for the storage of cold chain products, and must

8.8.1 not be sited in an environment where elevated temperatures will affect their performance.

8.8.2 Be monitored using a calibrated electronic min/max thermometer, with an accuracy of ±0.5C, which can be read without opening the refrigerator door

8.8.3 Have a temperature alarm fitted

EoC: there is a pharmaceutical fridge in use in the warehouse which complies with 8.8.1 to 8.8.3

8.9 The warehouse should be temperature mapped every 2 to 3 years to determine the temperature distribution under extremes of external temperature. Medicines should not be

stored in areas shown by temperature mapping to be unsuitable, e.g., at high level in poorly insulated stores.

EoC: There is evidence that the warehouse is temperature mapped every 2 to 3 years or following any major changes in the layout or storage solutions.

Element 9 Warehouse Transport

Introduction

Following dispatch from a manufacturing facility, the distribution chain for medicinal products can be complex, potentially involving a number of storage locations, wholesalers and modes of transport, before the product finally reaches the pharmacy.

Element 9 Warehouse Transport - Minimum Criteria Standards

9.1 Products should be packed in such a way as to ensure that the required temperatures are maintained throughout the journey and the medicines are transported in accordance with their manufacturers and labeling requirements to prevent jeopardizing their quality.

EoC: There is evidence that product packaging is robust and products are transported according to the manufacturer's instructions.

9.2 Temperature and humidity records, either of the vehicle or the actual product, through temperature and humidity loggers, must be available. The temperature and humidity records for each consignment should be reviewed and there should be a procedure for implementing corrective action in the proposal of adverse events.

EoC: Temperature and humidity records are being maintained and available when each consignment of products are transported in vehicles across Bahrain.

9.3 Products are inspected before and after transportation to assure quality is maintained.

EoC: Records are maintained and available for inspection of all products damaged during transportation.

9.4 All temperature and humidity recording devices should be calibrated annually against a certificated standard.

EoC: There is evidence that the temperature and humidity recording devices are calibrated and tested annually

9.5 Distributors should also ensure that consignments of refrigerated goods are clearly labeled with the required storage and transport conditions to be maintained.

EoC: There is evidence that all consignments requiring refrigerated transport are clearly labeled

9.6 When wholesalers employ couriers, they must have a technical agreement with their chosen courier in order to ensure that the courier also adheres to the above.

EoC: There is evidence of a technical agreement/contract with the chosen courier.

Glossary

Access- A person's ability to get necessary pharmacy services when needed. The ease of access is determined by components such as the availability of medications, the locale of pharmacy facilities, transportation, and hours of operation.

Accountability -The ability of a system to track an individual's dispensing actions and medications dispensed.

Accreditation- A formal process by which a recognized body ("accrediting body") assesses and recognizes that an organization meets applicable, pre-determined standards.

Aggregate- To combine standardized data/information.

Appropriateness -Extent to which a particular procedure, treatment, test or service is effective, clearly indicated, not excessive, adequate in quantity, and provided in the setting best suited to the client needs.

Availability- The degree to which appropriate care/service is available to meet the individual patient needs.

Benchmarking- A continuous process of measuring products, services, and/or practices against the competition in order to find and implement best practices.

Clinical Practice Guidelines- Statements that help practitioners and patients choose appropriate health care/services/treatments for specific clinical conditions.

Code of Conduct -A set of principles and expected behaviours that are expectations of employee performance within a health care setting or as defined by the leadership group.

Collaborative- An organizational culture characterized by a shared vision, shared leadership, empowered workers, and cooperation among organizational units as they work to improve process.

Competence- Job knowledge, skills, and attitude required to perform the job. Knowledge is the understanding of facts and procedures. Skill is the ability to perform specific actions.

Committee -A multidisciplinary body of persons officially delegated to consider, investigate, take action on, or report on some matter or perform a specified function.

Confidentiality- The restricted access to data and information to individuals who have a need, a reason, and permission for such access. An individual's right to personal and informational privacy, including his or her health care records.

Continuity of Care -A performance dimension addressing the degree to which the care for a patient is coordinated among practitioners and organizations and over time, without interruption, cessation, or unnecessary repetition of diagnosis or treatment.

Continuous Quality Improvement (CQI) -The culture, strategies and methods necessary for continual improvement in meeting and exceeding customer expectations.

Continuous Quality Improvement Tools -CQI tools focus on process rather than the individual, and promote the need to analyze and improve process.

Credentialing -The process of obtaining, verifying and assessing the qualifications of a health care professional to determine if an individual can provide patient care services/treatments in or for a health care organization.

Criteria- Expected level(s) of achievement or specifications against which performance can be assessed.

Data- Raw facts and figures from which information can be generated.

Database- An organized, comprehensive collection of stored data.

Effectiveness- The degree to which care is provided in the correct manner, given the current state of knowledge, to achieve the desired or projected outcome for the patient.

Efficacy- The power to produce an effect, for example: Clinical trials in Medicine provide evidence or efficacy.

Evidence based Medicine -The practice of medicine or the use of healthcare interventions guided by or based on supportive scientific evidence.

Facilitate- To make easier.

Family or Responsible Person- The person(s) with a significant role in the patient's life. This may include a person(s) not legally related to the patient. This person(s) is often referred to as a surrogate decision maker if authorized to make care decisions for a patient if the patient loses decision-making ability.

Functional Status -The ability of individuals to take care of themselves physically and psychologically.

Formulary -An approved list of medications and associated information related to medication use. The list is subject to periodic review and modification.

Goal -A broadly stated or long-term outcome written as an overall statement relating to a philosophy, purpose, or desired outcome.

Governance- The function of determining the organization's direction, setting objectives, and developing policy to guide the organization in achieving its mission.

Governing Body- Collectively the individual(s), group, or agency that has ultimate authority, responsibility, and accountability for the overall strategic direction, methods of operations (management and planning), establishment of policies, maintenance of safety and quality of care of the organization.

Guidelines -Principles guiding or directing action.

Hazardous Materials -Substances, such as chemicals, that are dangerous to humans and other living organisms.

Hazardous Waste -Waste materials dangerous to humans and other living organisms. Such materials require special precautions for disposal, including medicinal products..

Healthcare-Associated Infections (HAIs) -Infections that patients acquire during the course of receiving treatment for other conditions or that healthcare workers acquire while performing their duties within a healthcare setting. Specific criteria must be met in order to define an infection as healthcare-associated.

Health Care Professional -Any person who has completed a course of study and is skilled in a field of health. This includes a physician, dentist, nurse, pharmacist or other healthcare professionals. Healthcare professionals are often licensed by a government agency or certified by a professional organization.

High Risk- High probability that severe injury will occur.

Incident- Events that are unusual, unexpected, may have an element of risk, or that may have a negative effect on patients, staff, or the organization.

Indicator- Performance measurement tool which is used as a guide to monitor, evaluate and improve the quality of patient care and service.

Information -An interpreted set of data; organized data that provides a basis for decision-making.

Information Management- The creation, use, sharing, and disposal of data or information across an organization. This practice is critical to the effective and efficient operation of organization activities.

Informed Consent- Person's voluntary agreement of one who has sufficient mental capacity with full knowledge of the risks involved, probable consequences, and the alternatives to make an informed decision. It allows a patient to balance the probable risks against the probable benefits of any potential care.

Job Description- A written statements that describe the duties, responsibilities, required qualifications of candidates, and reporting relationship and co-workers of a particular job.

Leaders -The identified and designated individuals who have the responsibility to oversee effective functioning of processes within a defined scope of services.

Management- Setting targets or goals for the future through planning and budgeting, establishing processes for achieving those targets, and allocating resources to accomplish those plans.

Mission- The reason or purpose for the existence of an organization or one of its components.

Mission statement- A written expression that states the purpose of an organization or one of its components.

Monitoring -A planned, systemic, ongoing process to gather, organize, and review data/information on a regular basis with the purpose of identifying changes in a situation.

MSDS (Material Safety Data Sheet) -A form containing data regarding the hazardous properties of chemicals and other hazardous agents.

Objectives -Concrete, measurable steps taken to achieve goals. Tampering

Organizational Chart- A diagram representing the structure of the organization and reporting relationship. It shows employee positions, reporting relationship, and lines of authority.

Orientation -The act of being oriented. The introductory process by which staff become familiar with all aspects of the work environment and their responsibilities.

Outcome- A broad term that is used to describe the end result of a service, practice, procedure, or intervention.

Patient- A patient is a person for whom the organization accepts responsibility for treatment, care and/or service. For CBAHI standards, a patient includes such designations as client, resident, and individual served.

Patient Assessment -The gathering of information in order to evaluate a person's health and health-care needs.

Patient Satisfaction -A measurement that obtains reports or ratings from patients about services received from an organization, hospital, physician, or healthcare provider.

PDCA -It is a scientific method utilized to improve processes. Acronym meaning: PLAN the improvement, DO the improvement, collect data and analyze data, CHECK and study the results, ACT to improve the process and hold gains. Also known as the Shewart cycle, Deming cycle, or learning cycle of change.

Personnel File -Collection of information about a staff member covering personnel issues such as licensure, certifications, leaves, appraisal reviews, and job description.

Plan -To formulate or describe the approach to achieving the goals related to improving the performance of the organization.

Policy -A policy is a written document which outlines the rules and expected performance of staff within the organization. Policies are dynamic and reflect current knowledge and practice and need to be reviewed on a regular basis.

Privileging- The process of reviewing an individual's credentials through credentials body to determine the authority and responsibility to be granted to a practitioner for making independent decisions to diagnose, initiate, alter, or terminate a regimen of medical or dental care. Privileging determines the physician's scope of practice in the organization determined by his/her competencies.

Procedure- A written set of instructions that describe the approved and recommended steps for a particular act or sequence of acts.

Process -A set of interrelated steps directed at one particular outcome.

Process Improvement- Mechanisms utilized to make improvements to a process through the use of continuous quality improvement methods.

Probationary period -The time period identified by the organization for determining if the employee is competent to perform his/her duties and continue employment with the organization. Generally, the time period of probation is 3 months.

Protocols-A plan, or set of steps, to be followed in a study, an investigation, or an intervention.

Psychosocial- Refers to one's psychological development in the context of a social environment. It is simply the individual's interaction with the environment which he finds himself and the dynamics or factors which influence the individual's "psyche".

Quality -The degree to which health services for individuals and population increases the likelihood of desired outcome and are consistent with current professional knowledge.

Quality Control -A management process through which performance is measured against expectations and corrective actions are taken.

Quality Improvement- Team Individuals (cross-department functions/services) knowledgeable about a particular aspect of care or service and commissioned to improve a process that has been identified as requiring attention.

Referral- The process by which a patient is sent (1) from one clinician to another clinician or specialist; or (2) from one setting or service to another or other resource, either for consultation or care that the referring source is not prepared or qualified to provide.

Risk- The combination of the assessment of magnitude of injury, or potential injury, with the probability that certain actions/events will occur.

Root Cause -The underlying reason for the occurrence of a problem.

Safe Care- The degree to which the risk of an intervention and the risk in the care environment are reduced for a patient and others, including the health care practitioners.

Scope of Service -The range of activities provided to the patients and/or other customers by the leadership, clinical, and support personnel. This describes the full range of services, the demographics (age groups, types of patients) diagnostics provided, therapeutic interventions provided, and the number of patients who are provided each service annually. All of the resource and competency requirements flow from the organization’s scope of service.

Screening- A system for examining and separating into different groups.

Screening Criteria -A set of standardized rules or tests applied to patient groups on which to use a preliminary judgment that further evaluation is warranted.

Sentinel- Event An event that, when noted, requires intensive assessment.

Standard -Statement of structure and process expectations necessary to enhance quality care.

Standardization- To confirm with a predetermined set of expectations.

Strategic Planning -A management tool to help an organization do a better job. It is disciplined effort to produce fundamental decisions and actions that shape what an organization is, what it does, and why it does it, with a focus on the future.

Structure Environmental- features which shape process and outcome: resources, money, equipment, supplies, staff, policies.

System -A group of related processes.

Team -A group of five to eight people consisting of a leader, facilitator, and members who are addressing an issue that impacts the operations of a process.

Terms of reference -A formal document approved by the leadership that outlines the roles/responsibilities of a committee. This document describes the expected performance of the committee, how often the committee is expected to meet, and also includes a list of the membership and alternates if needed.

Timely -The degree to which care is provided to the patient at the most beneficial or necessary time.

Transfer- The formal shifting of responsibility for the care of a patient from one care unit to another, one clinical service to another, one qualified practitioner to another, or one organization to another organization.

Trending- The evaluation of data collected over a period of time for the purpose of identifying patterns or changes.

Triage -A system of establishing the order in which acts are to be carried out in an emergency, prioritize patients by their problems, symptoms determining the order of being managed.

Turn Around Time -Initial time from the starting point to the end point. For example: For a stat order, the time the doctor's order was written, or stated, to the time it is carried out.

Utilization- The use, patterns of use, or rates of use of a specified health care service.

Values -The beliefs and philosophy within an organization that establish the basis for the operation and provides guidelines for daily behaviour.

Vision- Description of what the organization would like to be.

Further modifications will be communicated to the Ambulatory Care Facilities through later editions and amendments. If you have any comments or queries about the Licensing standards please contact:

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