SERVICE STANDARD 18

Pharmacy Services

PREAMBLE

The Pharmacy Services shall comprise all activities relating to safe and efficient delivery of one or more of the following activities:

- Procurement, storage, distribution and delivery of pharmaceutical products
- Manufacturing and reprocessing of pharmaceutical products
- Drug information, dissemination and patient counselling
- Poison information and advisory services
- Clinical pharmacy services

TOPIC 18.1: ORGANISATION AND MANAGEMENT

STANDARD 18.1.1

The Pharmacy Services shall be organised and administered to provide efficient pharmacy services including the purchase, distribution, and control of pharmaceutical products; and to disseminate appropriate drug information to the healthcare team and patients of the Facility in accordance with the prevailing standards of pharmacy practice.

CRITERIA FOR COMPLIANCE:

18.1.1.1 There are documented purposes which may be termed Vision and Mission Statements, Goals and Objectives that suit the scope of services.

Notes/Explanations

When compiling the purposes, consideration shall be given to the following:

a) They are what the services want to achieve.

b) They support the statement of purpose of the services.

c) They support and contribute to the goals of the Facility.

d) They are written and are consistent with professional standards and guidelines, and relevant legislation.

e) They are developed with input from patients, community, medical staff, all levels of service staff, and consultation with other relevant services.

f) They are monitored to determine if they are realistic and measurable.

g) They are reviewed and revised as necessary, and dated accordingly.
18.1.2 There is an organisation chart that:

a) provides a clear representation of the structure and reporting relationships of the services;

b) is accessible to all staff;

c) includes off-site services if applicable;

d) is revised when there is a major change in:

i) organisation;

ii) reporting relationships;

iii) goals and objectives;

iv) staffing patterns.

18.1.3 There are written and dated job descriptions for all classifications of staff that include:

a) qualifications, training, experience and certification required for the position;

b) lines of authority;

c) accountability, functions, and responsibilities;

d) a review when necessary or when there is a major change in:

i) nature and scope of work;

ii) duties and responsibilities;

iii) general and specific accountabilities;

iv) qualifications required;

v) staffing patterns;

vi) Statutory Regulations.

18.1.4 Regular staff meetings are held to discuss issues or matters pertaining to the operations of the department. Minutes are kept and are accessible to all staff.

18.1.5 Personnel records on training, leave etc are maintained for every staff.

18.1.6 The person in charge of the Pharmacy Services is involved in the planning, management, budgeting and resources utilisation.

18.1.7 The person in charge of the Pharmacy Services is involved in the formulation of all administrative decisions relating to the provision of pharmacy services and to the use of medicines.

18.1.8 The person in charge of the Pharmacy Services is involved in the appointment or assignment of staff.
18.1.1.9 The person in charge of the Pharmacy Services shall ensure the staff complete and forward incident and accident reports to the Chief Executive Officer or designate.

18.1.1.10 The pharmacy services provided include the purchasing and distribution of all pharmaceutical products, the provision of information and the practice of safety and quality improvement activities in relation to pharmaceutical products used in the Facility.

18.1.1.11 Specific services provided by the Pharmacy Services shall include, as appropriate, the following:

a) procurement and inventory control systems;

b) clinical pharmacy services such as total parenteral nutrition, clinical pharmacokinetics services, oncology pharmacy services, nuclear medicine services and quality dispensing of medicines in terms of dosage, indication for use, efficacy, adverse reactions, drug-drug and drug-food interactions, legal requirements and, where appropriate, cost analysis and pricing;

c) educational services pertaining to:

   i) medicines usage and counselling for patients;
   ii) drugs and drug therapy for medical, nursing, and other staff;
   iii) poison information and advisory services;
   iv) continuing education for pharmacy staff;

d) manufacturing and reprocessing of pharmaceutical products in accordance with Good Manufacturing Practice (GMP) guidelines;

Notes/Explanations

Reprocessing of pharmaceutical products that are not stored but issued for immediate use shall be exempted from this requirement.

Additionally, in cases where drugs are manufactured, such services shall have a licensed pharmacist and where applicable, manufacturing licence issued under the Control of Drugs and Cosmetics Regulations 1984 (P.U. (A) 223/1984):

   i) reconstitution of cytotoxic drugs in accordance with Good Manufacturing Practice (GMP) guidelines;
   ii) preparation of radiopharmaceuticals in accordance with Good Manufacturing Practice (GMP) guidelines;
   iii) conduct research in pharmacy services to improve medicines related therapy and utilisation;
   iv) storage and dispensing of psychotropic substances shall be in accordance with the provisions of Poisons (Psychotropic Substances) Regulations (1989) as in the Third Schedule of the Poisons Act 1952.
18.1.1.12 Where there are decentralised sections of the Pharmacy Services, specific objectives are documented.

18.1.1.13 Statistics and records shall be maintained and used for managing the Pharmacy Services and patient care purposes.

18.1.1.14 Pharmacy Services shall be represented on multi-disciplinary committees and ad hoc teams where pharmacy matters are discussed.

18.1.1.15 Pharmacy Services maintain good communication with general administration, medical professionals, and nursing administration; and staff of the Pharmacy Services participate in education programmes, inter-departmental meetings and committees.
TOPIC 18.2: HUMAN RESOURCE DEVELOPMENT AND MANAGEMENT

STANDARD 18.2.1

The Pharmacy Services shall be managed by a suitably qualified, experienced and registered pharmacist; and supported by other registered pharmacists, pharmacy assistants and other supporting staff to achieve the objectives of the services.

CRITERIA FOR COMPLIANCE:

18.2.1.1 The Pharmacy Services is directed by registered pharmacists who are currently registered with the Pharmacy Board of Malaysia and where applicable possess valid licence/permit from relevant statutory authorities.

18.2.1.2 The staffing of the Pharmacy Services is mainly provided by competent individuals qualified by education, training and experience to meet the demands of the position and to achieve the objectives of the services.

18.2.1.3 The authority and accountabilities of the person in charge are clearly delineated.

18.2.1.4 The person in charge of the Pharmacy Services is involved in the appointment or assignment of staff for all the activities of the Pharmacy Services.

18.2.1.5 The person in charge of the Pharmacy Services is responsible for upholding the laws regulating the practice of pharmacy and the control and distribution of pharmaceuticals products. He or she is also responsible for appropriate liaison with the governing authorities administering these laws.

18.2.1.6 Sufficient numbers of competent personnel and support staff are employed to enable the services to meet the documented purposes.

18.2.1.7 There is a structured orientation programme where new staff are briefed on pharmacy services and relevant aspects of the Facility to prepare them for their roles and responsibilities.

18.2.1.8 Staff receive written appraisals of their performance at the completion of the probationary period and annually thereafter, or as defined by the Facility.

18.2.1.9 There are continuing professional development activities for staff to pursue professional interests. There is evidence that staff education and development needs have been appraised and identified.

18.2.1.10 At all times there is at least a suitably qualified pharmacist on duty or on call.
TOPIC 18.3: POLICIES AND PROCEDURES

STANDARD 18.3.1

There are documented policies and procedures for the core business of the Pharmacy Services to achieve its goals and objectives. Policies and procedures shall be consistent with the relevant regulations and legal requirements of relevant government agencies.

CRITERIA FOR COMPLIANCE:

18.3.1.1 There are written and dated policies and procedures for the core business of the Pharmacy Services. These policies and procedures reflect current laws and standards of pharmacy practice, requirements of statutory authorities, and the objectives of the services and are consistent with the overall policies of the Facility.

18.3.1.2 Policies and procedures are developed in collaboration with all staff, such as medical staff, management, and other internal and external service providers; and with reference to applicable governing standards or authorities.

18.3.1.3 New and revised policies and procedures are communicated and made accessible to all relevant staff.

18.3.1.4 There is evidence of compliance with policies and procedures.

18.3.1.5 Policies and procedures are reviewed at least every three years, revised and dated accordingly.

18.3.1.6 Policies and procedures of the Pharmacy Services are consistent with related policies and procedures of other services.

Notes/Explanations

Policies and procedures of the Pharmacy Services shall cover the following:

a) Ordering and administering of medicines:

   i) incorporation of inpatient and outpatient medication orders into the patient’s medical records;
   ii) listing of medicines that may be administered by the nursing staff without a medical practitioner’s order;
   iii) recording in the patient’s medical record for every dose of medicines administered;
   iv) keeping accurate and accessible records of medicines supplied and administered to inpatients and outpatients;
   v) administering of medicines brought into the Facility by patients;
   vi) administering of medicines by patients, where appropriate;
   vii) access to patients’ medical records, where appropriate;
   viii) abbreviations where used is in accordance with an approved list.
b) Patient education/counselling:
   i) explanation and instructions by a pharmacist on the use and storage of medications;
   ii) provision of education and counselling as appropriate to patients and their families relating to medicines prescribed.

c) Manufacturing, reprocessing and storage:
   i) preparation of parenteral nutrition and their labelling;
   ii) intravenous and reconstitution services;
   iii) reconstitution, handling and disposal of cytotoxic drugs;
   iv) preparation, handling and disposal of radiopharmaceuticals;
   v) re-packaging and pre-packaging medicines;
   vi) labelling of medicines;
   vii) storage of all medicines within the Facility with respect to statutory regulations and any other requirements;
   viii) inventory control systems;
   ix) provision of emergency services outside normal pharmacy hours;
   x) disposal of discontinued, out-dated, unwanted or unused portions of medicines;
   xi) guideline on spillage and contamination of staff.

d) Drug/poison information and advisory services:
   i) active dissemination and provision of drug information to healthcare professionals.

e) Adverse drug reaction reporting:
   i) participation by the pharmacist in the adverse drug reaction reporting system of the Facility. Such policies and procedures shall include the method of detection, a mechanism for reporting to the medical practitioner, the pharmacist, the appropriate internal committee and the Adverse Drug Reaction Advisory Committee; and a mechanism for the inclusion of the report in the patient’s medical records.

f) Monitoring and controlling of sample medicines:
   i) Monitoring and control of sample medicines brought into the Facility.

g) Others:
   i) drug recall procedure;
   ii) security of the Pharmacy Services and storage areas at all times;
   iii) drug complaints procedure;
   iv) dispensing, storage and handling of psychotropic drugs.

18.3.1.7 Copies of relevant regulations and requirements of statutory authorities are available to staff.
18.3.1.8 Medicines are dispensed based on written order from the medical practitioner (or duplicate where legally permissible). Drug orders shall not be transcribed, and drugs are administered only based on the original of the medical practitioner’s order.

18.3.1.9 Telephone or other electronic means for ordering of medicines is limited to exceptional circumstances as defined by regulations and policy of the Facility. If such ordering is accepted, written confirmation by the prescribing medical practitioner shall be obtained within 24 hours.

*Notes/Explanations*

This does not apply to online or secure ordering where the prescriber may be authenticated.

18.3.1.10 There is a system for documentation of medication errors, incidents, and patient’s complaints and recording of action taken to identify and correct the cause of these problems.
TOPIC 18.4: FACILITIES AND EQUIPMENT

STANDARD 18.4.1

Adequate and appropriate space, equipment, and supplies shall be provided for the Pharmacy Services to fulfil its administrative, professional, and technical functions.

CRITERIA FOR COMPLIANCE:

18.4.1.1 Adequate and safe storage facilities are provided in the Pharmacy Services to ensure that all pharmaceuticals and related substances are kept under conditions of Good Storage Practice guidelines that include:

a) Protection of the stored materials from all potentially harmful influences, such as undue variations in temperature and humidity, dust and odour, entry of animals, vermin and insects.

b) Areas shall be sufficiently large, and if necessary, shall have physically separated zones for orderly segregated storage.

c) Special precautions for the storage of hazardous, sensitive, or dangerous materials such as combustible liquids and solids, pressurised gases or liquids, narcotics and other potent habit-forming substances, highly toxic substances, radioactive materials, herbal drugs and remedies.

d) Special facilities shall be constructed and equipped for materials requiring specific storage conditions relating to temperature, humidity and other physical conditions.

e) Where controlled environmental storage conditions are required, these conditions shall be continually monitored and appropriate corrective action shall be taken where necessary. The desired conditions shall include:

   i) Temperature Control: The following definition may be adopted:
      • Cold place, the temperature does not exceed 8°C
      • Refrigerator, temperature between 2 - 8°C
      • Freezer, temperature not higher than 0°C
      • Cool place, temperature between 8 - 25°C
      • Room temperature, temperature between 15 - 30°

   ii) Humidity
      • Materials requiring dry or humidity control storage shall be stored in areas where the relative humidity and temperature is maintained within prescribed limits.

f) The equipment used for measuring and monitoring shall be checked at suitable predetermined intervals and the results of such checks shall be recorded and retained.
g) Facilities for storing any psychotropic substances shall be locked and unlocked by the person authorised to handle such substances and the keys to such facilities shall be kept by him only in accordance with the Poisons (Psychotropic Substances) Regulations (1989).

18.4.1.2 There are adequate space, facilities and equipment for the administrative, professional, and technical functions of the Pharmacy Services.

18.4.1.3 There are adequate space, facilities, and equipment in the Pharmacy Services for compounding, re-packaging, or reprocessing and dispensing of drug products including parenteral, oncological nuclear medicine preparations where appropriate. Designated and properly equipped areas are provided for the following:

a) Preparation of cytotoxic drugs in accordance with the requirements of the authorities. The Pharmacy Services shall ensure that cytotoxic waste materials are contained and disposed of in a safe and approved manner.

b) Regular dispensing functions including extemporaneous dispensing.

c) Manufacturing and re-processing of bulk non-sterile products in accordance with statutory regulations and Good Manufacturing Practice (GMP) guidelines.

d) Preparation of sterile products and intravenous additives in accordance with statutory regulations and Good Manufacturing Practice (GMP) guidelines.

e) Preparation of radiopharmaceuticals in accordance with statutory regulations and Good Manufacturing Practice (GMP) guidelines.

f) Quality control procedures to be carried out on products prepared in the Pharmacy Services.

18.4.1.4 Pharmacy security shall address both facilities and staff protection including proper access controls and equipment such as duress alarms.

18.4.1.5 There is documented evidence that equipment complies, where applicable, with relevant standards, e.g., those set by SIRIM Berhad.

18.4.1.6 There is documented evidence that the equipment is maintained and calibrated regularly.

18.4.1.7 Where specialised equipment is used, there is evidence that only appropriately qualified staff operate such equipment.
TOPIC 18.5: SAFETY AND QUALITY IMPROVEMENT ACTIVITIES

STANDARD 18.5.1

The Pharmacy Services shall ensure the provision of high quality performance with its ongoing involvement in the safety and quality improvement activities of the Facility.

CRITERIA FOR COMPLIANCE:

18.5.1.1 There are planned and systematic safety and quality improvement activities in place for monitoring and evaluating the performance of the Pharmacy Services.

18.5.1.2 There are safety and quality improvement activities in place which support the Facility-wide safety and quality improvement activities that include tracking and trending of specific performance indicators.

18.5.1.3 There are clearly assigned responsibilities for safety and quality improvement activities within the services.

18.5.1.4 Appropriate documentation of safety and quality improvement activities is kept and confidentiality of staff and patients is preserved.