CES 191 Compulsory Ethiopian Standard

Second Edition

xx-xx-2024

Medium clinic in organization -Requirement

ICS: 71.100.40

Published by Institute of Ethiopian Standards

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FOREWORD

This Ethiopian Standard has been prepared under the direction of the Technical Committee for Medical Science & Health care practices (TC 90) and published by the Institute of Ethiopian Standards (IES).

This Ethiopian Standard cancels and replaces CES 191:2018, Medium clinic in organization -Requirement.

Application of this standard is COMPULSORY with respect to clause 4 and 5. A Compulsory Ethiopian standard shall have the same meaning, interpretation and application of a “Technical Regulation “as implied in the WTO-TBT Agreement.

Implementation of this standard shall be effective as of xx-xx-2024.

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Medium clinic in organization -Requirement

1 Scope

The document covers the minimum requirements with respect to practices, premises, professionals and products or materials put into use for health care service Medium clinic.

This requirement is applicable for all new and existing Medium clinics in an organization (private, governmental and non-governmental.)

2 Normative References

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

CES 246 - Health institutions–General requirement

3 Terms and Definitions

For the purpose of this standard the following terms and definitions shall apply.

3.1
appropriate organ
a state government organ authorized to implement food, medicine and healthcare administration and control activities at a state level;

3.2
authority
the Ethiopian Food, Medicine and Healthcare Administration and Control Authority.

3.3
proclamation
the Ethiopian Food, Medicine and Healthcare Administration and Control proclamation No 661/2009.

3.4
appropriate law
a law issued by a state to implement regulatory activities regarding food, medicine and healthcare.

3.5
person
any physical or juridical person

3.6
authorized person
any medium clinic staff who is responsible for a given service

3.7
other governmental organizations/ Clinic in organizations
organizations that include Universities, factories and any organizations that have medium clinic to deliver service for the staff and/or the staff"s families without any price.

3.8
medium Clinic in organization:
the next level to primary level of the healthcare in ambulatory health service that provide mainly preventive, promotive and curative services in organization.

4 General requirement

4.1 The medium clinic shall full fill the health institutions general requirement specified in CES 246.

4.2 The clinic shall provide service only at outpatient/ambulatory level at least for working hours.

4.3 Emergency care with qualified staff shall be available during organization working hours.

4.4 The medium clinic shall avail updated reference materials, treatment guidelines and manuals for common disease.

4.5 Diseases under national surveillance shall be notified to the FMOH through the proper reporting channel.

4.6 The medical record for patients shall include, but not limited to,

a) Pertinent history and physical examination
b) Documentation of Growth assessment: record of weight & height or length,
c) Documentation of a basic developmental assessment: sensory screenings, cognitive, &
d) Record of immunization status.

4.7 The medium clinic should have a program of continuous quality improvement for the service which includes regularly collecting and analyzing data to help identify health-service problems and their extent, and recommending, implementing, and monitoring corrective actions on the basis of these data.

4.8 There shall be a mechanism of quality improvement for the service at least by collecting feedback from clients and having a formal administrative channel through which clients lodge their complaints and present their grievances.

4.9 The clinic shall assign quality focal person to improve quality of service deliveries.

4.10 The medium clinic shall asses its staffs current knowledge and practice and observes utilization of national guidelines for the services it renders every six month.

4.11 The medium clinic shall provide or facilitate training to their staffs.

4.12 The medium clinic shall display the following at visible place:

a) List of Services available in the medium clinic during working hours & after working hours,
b) List of Professionals working in the clinic during & after working hours,

4.13 The medium clinic facilities shall be well marked and easily accessible for persons with disability.

4.14 Potential source of accidents shall be identified and acted upon like slippery floors, misfit in doorways and footsteps.

4.15 The circulation ways and sub corridors shall be a minimum 1.5 m wide.

4.16 Patient serving corridors shall not be less than 2 m wide.

4.17 Glass doors shall be marked to avoid accidental collision.

4.18 Medium clinic where functional units are at different floor shall have a mechanism of accessing all the functioning rooms horizontally either by stairs and ramp or stair and elevator.

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5 Service requirements

5.1 General outpatient Medical Practices:

5.1.1 Practices

5.1.1.1 The medium clinic shall provide outpatient care (diagnosis & treatment) for ambulatory patients & treatment of acute conditions.

5.1.1.2 The clinic shall provide assessment, diagnosis, follow up & referral of ambulatory patients with common and chronic conditions including TB, HIV to appropriate level;

5.1.1.3 The clinic may Provide basic MCH services: ANC, identifying high risk pregnancy & referral, post natal care,

5.1.1.4 The clinic shall provide routine examinations and treat acute illnesses, and provide referral for dentist, ophthalmologist, and provide Mental health services which will be provided in an integrated manner (by general practitioner and/or health officer or BSc nurse).

5.1.1.5 The general medical service shall be available in working days for at least eight hours a day during regular working hours.

5.1.1.6 The medical assessment at OPD level shall include;

a) Comprehensive medical and social history
b) Physical examination including at least:
   - Vital sign (BP, PR, RR, T^{o}, Pain assessment) and weight
   - Clinical examination pertinent to the illness
c) Diagnostics impression
d) Laboratory and other medical workups when indicated.

5.1.1.7 The range of relevant treatment options and the clinical impression shall be fully described to client and/or their families and documented accordingly

5.1.1.8 The medium clinic shall have clinical protocols for management of at least common disease entities like malaria, hypertension, locally significant disease dental, eye, ENT and mental health problems in line with the national and or international guidelines.

5.1.1.9 The service shall avail national guidelines for malaria, TB/Leprosy, HIV, VCT, PICT, trachoma, pain management, STI and other common illnesses.

5.1.1.10 The general medical service shall have functional referral system which include at least:

a) Conditions indicative for urgent referral,
b) Procedure for selection of cases and referring patients directly to respective services.
c) List of potential referral sites with contact address (referral directory) with regular update.
d) Referral forms.
e) Referral tracing mechanism (linkage).
f) Feedback providing mechanism.
g) Documentation of referred clients

5.1.1.11 The medium clinic shall have a system to report diseases under national surveillance to the sub-city/woreda/town health offices.

5.1.1.12 The medium clinic shall provide information on rehabilitative services as part of integrated general medical service including contracture and foot ulcer prevention. There shall be patient education on prevention of:

a) pressure sores in clients with sensory loss,
b) contractures in clients with limb and/or trunk paralysis,
c) Manageable rehabilitation service can be rendered optionally.

5.1.1.13 Specific public health program related service/intervention packages may be delivered in medium clinic upon approval if supported with additional trainings.

5.2 Minor Surgical service

5.2.1 Practice

5.2.1.1 The Medium clinic shall provide minor surgical services for the following conditions:

a) Circumcisions,
b) Lipoma and simple cyst excisions,
c) abscess drainages,
d) suturing of lacerated wounds ,
e) external immobilization of closed and open fractures,
f) foreign body removal and
g) other minor interventions under local anesthesia

5.2.1.2 The medium clinic shall have clear protocol for minor surgical procedures to be done at outpatient level.

5.2.1.3 Surgical interventions shall be recorded for each patient and documentation shall be integrated with the patient's medical record.

5.2.1.4 The preoperative diagnosis shall be recorded in the medical record for all patients prior to minor surgery.

5.2.1.5 The health professional shall explain the disease condition, minor surgical procedure and outcome possibilities in clear, simple and understandable terms to the patient and/or next of kin or family.

5.2.1.6 There shall be processes and procedures that ensure that minor surgical procedures shall be done under aseptic technique.

5.2.1.7 The medium clinic shall have a copy of management protocols from the national/international document for at least for the following:

a) Acute burn management
b) pain management
c) emergency or acute trauma management
d) emergency resuscitation(CPR)

5.2.1.8 The minor surgical procedure room shall be kept clean at all times.

5.2.1.9 There shall be a written policy about administration of local anesthesia in the medium clinic.

5.2.1.10 During and after a minor surgical procedure pain shall be assessed and controlled by GP or HO or BSc nurse.

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5.3 Nursing care service practices

5.3.1 Practice

5.3.1.1 Nursing care shall be availed for patients, and other clients who need the care.

5.3.1.2 Written copies of nursing procedure manual shall be available to the nursing staff. The manual shall be used at least to:

a) Provide a basis for induction of newly employed nurse(s),
b) Provide a ready reference on procedures for all nursing personnel.
c) Standardize procedure and practice.
d) Provide a basis for continued professional development in nursing procedures/techniques.

5.3.1.3 The medium clinic shall establish system for verbal and written communication about patient care that involves nurses.

5.3.1.4 There shall be a procedure for standardized, safe and proper administration of medications by nurses or designated clinical staff including proper documentation.

5.3.1.5 All patients kept for observation/resuscitation shall be under the supervised care of a nurse at all times.

5.3.1.6 Copies of Nurses" code of professional practice shall be available and nurses shall abide by their code of professional practice relevant to their professional role.

5.3.1.7 Allergies shall be listed on the front cover of the patient's chart or in a computerized system, highlighted on the screen.

5.3.1.8 Nursing personnel shall administer medications prescribed by physician and/or authorized independent practitioner in accordance with order prescribed and Codes of Professional Conduct and Ethics.

5.4 Emergency service

5.4.1 Practices

5.4.1.1 The emergency service shall be available during the organizational working hours of the medium clinic.

5.4.1.2 Examination room(s) shall be ready and accessible for emergency at all times.

5.4.1.3 Life saving management of emergency cases shall be provided without any prerequisite and discrimination.

5.4.1.4 The emergency service shall provide basic life support as indicated for any emergency cases, which may include at least for of the followings :

a) Airway management,
b) Bleeding control
c) Fluid resuscitation
d) Cardiopulmonary resuscitation (CPR)

5.4.1.5 There shall be a written protocol for emergency services and the provision of this service shall be done in accordance with the clinical protocols of the service.

5.4.1.6 Protocols for initial management of at least the following emergency cases:

a) Shock
b) Severe Bleeding

c) Fracture and injuries
d) Coma
e) Burn
f) Poisoning
g) Seizure disorder
h) Hypertension emergencies
i) Cereberovascular accident
j) Acute diarrhea (Severe dehydration)
k) Acute abdomen
l) Tetanus
m) Meningitis
n) Severe & complicated malaria

5.4.1.7 If referral is needed it shall be done after providing initial stabilization and after confirmation of the required service availability in the facility where the patient is to be referred to.

5.4.1.8 If the patient to be referred needs to be attended by a health professional during the transfer process, the Medium clinic has the responsibility of assigning the accompanying professional.

5.4.1.9 Every procedure, medication and clinical condition shall be communicated to the patient or family member or next of kin after responding for urgent resuscitation measures.

5.5 Delivery and MCH service practices (Optional)

5.5.1 Practice

5.5.1.1 The medium clinic shall provide delivery service for spontaneous normal deliveries.

5.5.1.2 There shall be a reliable referral system for high-risk mothers and complicated deliveries.

5.5.1.3 Instrumental assisted deliveries are prohibited in medium clinic

5.5.1.4 The medium clinic shall provide MCH services that include ANC, PNC, Family Planning, Growth monitoring, VCT and PMTCT services being compliant with the current guidelines prepared for the respective services.

5.5.2 Premises

5.5.2.1 The medium clinic facility shall have dedicated territory or compound with entrances and secured from stray animals.

5.5.2.2 All rooms shall have adequate light, water and ventilation.

5.5.2.3 The examination rooms shall promote patient dignity and privacy.

5.5.2.4 The arrangement of rooms shall consider proximity between related services.

5.5.2.5 The medium clinic shall have IEC and entertaining materials in the waiting area.

5.5.2.6 The medium clinic may have fire extinguisher placed in visible area

5.5.2.7 The medium clinic shall have hand washing basin at patient care rooms (Examination room(s), treatment room, Laboratory, toilet room, Delivery room if any)

5.5.2.8 The corridor to examination rooms shall not be less than 1.5m, to allow easy transport of emergency patients.

5.5.2.9 The medium clinic shall have a minimum of the following premises set up:

Table 1- Premises required for the medium clinic

Premises required	No. of rooms required	Area required
Reception, Registration/ Recording & Waiting area	1	16 sq. m
Examination room	1	12 sq. m
Laboring, Delivery and Postnatal rooms (Optional) Delivery 16 sq. m,	3	40 sq. m

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Laboring 12 sq. m & Postnatal 12 sq. m		
MCH room (Optional)	1	12 sq. m
Treatment/ procedure/ injection room,	1	12 sq. m
Laboratory room	1	20 sq. m
Pharmacy service		
o Medicines shelve, working space, dispensing counter , patient waiting area and Counseling area	1	20sq. m
o Pharmacy store	1	16 sq. m
X-ray room as per ERPA requirements (optional)		
• Conventional X-ray room	1	24 sq. m
• Dark room (if necessary)	1	6 sq. m
• Toilet with hand washing basin	2	8 sq. m
• Patient dressing cubicle inside x-ray room	1	4 sq. m
• sub waiting area	1	12 sq. m
Ultrasound room(Optional)	1	9 sq. m
Emergency resuscitation room with two beds	1	16 sq. m
Instrument processing room	1	9sq. m
Staff room	1	
Toilets (Male &Female)	2	
Shower room	1	

5.5.3 Professionals

5.5.3.1 The medium clinic shall be directed by a licensed

a) General Practitioner or

b) Health officer or

c) BSc Nurse

5.5.3.2 Where a medium clinic is run by a GP or HO or BSc Nurse, the service available shall be limited to the scope of work of the respective professional provided by the appropriate regulatory body.

5.5.3.3 The medium clinic shall have at a minimum the following staff:

Table 2- Professionals required for the medium clinic

Staffs required	Number required
GP or HO or BSc Nurse	1
Nurse(clinical / BSc Nurse)	2
Midwives(optional)	1
Pharmacist /pharmacy technician	2
Laboratory technician or Laboratory technologist	2
Radiology professional or Radiographer (optional)	1
Receptionist	1
Cleaner	1

5.5.3.4 There shall be written discrete job descriptions that detail the roles and responsibilities of all clinic personnel.

5.5.4Products

5.5.4.1 Medium clinic shall have the following equipments and supplies:

a)Diagnostic Equipments:

- Stethoscope
- Sphygmomanometer
- Thermometer
- Weighing scale and height scale
- Infanto-meter(optional)
- Otoscope
- Glucometer
- Ophthalmoscope
- Reflex hammer
- Feto scope
- Snellen`s Chart
- Pulse oxymetry
- Tuning fork

b)Medical Equipment

- Mobile examination lamp
- Examination couches
- Sterilizer (steam and/ or dry) with stri -strip
- Refrigerator #2, (LAB & Treatment room)
- Oxygen source with flow meter and nasal prong
- Suction machine

c)Delivery Equipment (optional)

- Suction machine (shared)
- Delivery coach
- Neonatal resuscitation kit
- Feto scope
- Delivery set

d)Instruments

- Resuscitation sets
- Dressing set
- Minor surgical set
- Enema set
- Specula of different sizes
- Pickup forceps with jar
- Sterilization drums
- Kidney dishes
- Splint different type
- Collars
- Urinary catheter
- Instrument tray
- Instrument trolley
- Ear irrigation syringe
- Packing nasal forceps,
- Steri-strip for steam autoclave
- Lumbar puncture set (optional)
- IV Infusion stand

e)Others

- Tourniquet
- Drapes
- Surgical cape
- Surgical mask
- Kick buckets
- Tongue depressors
- Cabinets and shelves
- Time clock

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5.5.4.2 Emergency medicines shall be available as per emergency medicine list prepared by EFDA.

5.6 Laboratory service

5.6.1 Practices

5.6.1.1 Medium clinic shall have a laboratory service during working hours.

5.6.1.2 The following list of lab tests shall be available in the medium clinic:

a) **HEMATOLOGY**

- White blood cell count
- Hemoglobin
- Hematocrit
- Differential count
- Hemoparasite
- Platelet
- Erythrocytic Sedimentation Rate (ESR)
- RBC morphology
- Blood group & Rh

b) CLINICAL CHEMISTRY

- Glucose
- Uric Acid
- Creatinine
- Urea/ BUN
- Alkaline Phosphatase
- Aspartate Aminotransferase (AST) (option)
- Alanine Aminotransferase (ALT) (option)
- Bilirubin, Direct
- Bilirubin, Total

c) URINE AND BODY FLUID ANALYSIS

- Urine analysis Qualitative
- Urine Microscopy
- Pregnancy test

d) PARASITOLOGY

- Stool Examination

e) BACTERIOLOGICAL/ FUNGAL EXAMINATION

- Gram Stain
- AFB Stain
- KOH
- Wet mount

f) SEROLOGICAL TESTS

- Widal-weli fliex
- HBsAg
- RPR/ VDRL (syphilis)
- HIV Ab test (According to the national algorithm)

5.6.1.3 All equipment in the laboratory of medium clinic shall be in good working order, routinely quality controlled, and precise in terms of calibration.

5.6.1.4 The laboratory shall have written policies and procedures and include at least the followings:

a) Procedure manuals (Standard Operating Procedure, SOP) or guidelines for all tests and equipments,

b) Report times for results (Established turnaround time),

c)Quality assurance and control processes,

d)Inspection, maintenance, calibration, and testing of all equipment,

e)Management of reagents: including availability, storage, and testing for accuracy,

f) Procedures for identifying, collecting, processing and disposing of specimens,

g)All normal ranges for all tests shall be stated,

h)Laboratory safety program: including infection control, preventive maintenance,

i) Documentation of quality control data: calibration report, internal and external quality control, refrigerator readings,

5.6.1.5 The medium clinic laboratory shall maintain documentations for the implementation of the above mentioned policies/ procedures

5.6.1.6 The laboratory shall have procedures or (SOP) for proper specimen collection that address specific collection requirements such as:

a)Preferred sample type (venous, arterial, capillary, urine, spinal fluid),

b)Type of test tubes/ anticoagulant,

c)Sample volume,

d)Patient identification,

e)Requirements for patient preparation and storage condition of specimens.

5.6.1.7 The laboratory shall follow standard operating procedures (SOP) and conduct routine quality assessments to ensure reliable and cost-effective testing of patient specimens.

5.6.1.8 The right patient with the right request form shall be identified during collection and delivery of result.

5.6.1.9 Requests for testing shall provide:

a)The name of the ordering physician or other person authorized to order testing,

b)Address of the clinic,

c)Type of sample collected,

d)The anatomic site where appropriate

e)The test requested

f) Patient ID, name, age and sex

g)Clinical Diagnosis: Pertinent clinical information as appropriate for purposes of test interpretation

h)Date and time of sample collection and receipt in the laboratory,

5.6.1.10 There shall be SOP or criteria developed for acceptance or rejection of clinical samples.

5.6.1.11 The laboratory shall maintain a record of all samples received.

5.6.1.12 Laboratory shall have a SOP for storage of clinical samples if it is not immediately examined.

5.6.1.13 Laboratory report

a)All laboratory test result/reports shall have reference (normal) ranges specific for age and sex.

b)Documentation or Transcription files of reported results shall be retained by the laboratory for retrieval of the information when needed.

c)In the case of laboratory tests performed by an outside laboratory, the original report from such laboratory shall be contained in the medical record.

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d)Quality assured test results shall be reported on standard forms to the physician with the following minimum information:

- Patient identification (patient name, age, sex)
- Date and time of specimen collection
- The test performed and date of report.
- The reference or normal range.
- The laboratory interpretation where appropriate,
- The name and initial of the person who performed the test and released the result.
- Facility address.

e)Laboratory results shall be legible, without transcription mistakes and reported only to persons authorized to receive them such as the ordering physician or the nursing staff.

5.6.1.14 Safe disposal of samples shall be after decontamination in line with standards prescribed under infection prevention.

5.6.1.15 Wearing of protective clothing of an approved design (splash proof), always fastened, within the laboratory work area and removed before leaving the laboratory work area

5.6.1.16 Where services are provided by an outside laboratory, the conditions, procedures, and availability of services offered shall be available in writing in the medium clinic.

5.6.2Premises

5.6.2.1 The medium clinic shall have 1 room with 20 sq. m for basic laboratory service with the necessary space, facilities and equipment to perform tests.

a)Reception desk with patient waiting area

b)Bacteriology, Parasitological and urinalysis section

c)Hematology, serology section

d)Working area

5.6.2.2 The laboratory shall provide safety, adequate lighting, ventilation, waste and refuse disposal system.

5.6.2.3 Work areas shall be clean and well maintained.

5.6.2.4 The laboratory shall have controlled temperature of refrigerator for reagents, blood sample, calibrator, control materials.

5.6.2.5 There shall be cupboard for reagents that shall be kept at room temperature.

5.6.2.6 The laboratory facilities shall meet at least the following:

a)The laboratory shall have a reliable supply of running water. At least two sinks in separate area shall be provided in the room, one for general laboratory use and the other reserved for hand washing. (and at least 1000L reserve tank in case of interruption).

b)Continuous power supply

c)Working surface/ Bench tops shall be covered with appropriate water and corrosive resistance materials

d)Internal surfaces, i.e. of floors, walls, and ceilings shall be :

- Smooth, impervious, free from cracks, recesses, projecting ledges and other features that could harbor dust or spillage
- Easy to clean and decontaminate effectively

e)Constructed of materials that are non-combustible or have high fire-resistance and low flame-spread characteristics.

f) Lockable doors and cupboards

g)Closed drainage from laboratory sinks

5.6.3Professionals

5.6.3.1 The laboratory of medium clinic shall be directed by a licensed medical Laboratory technologist /Technician.

5.6.3.2 The clinic shall have Medical Laboratory technologist/ technician #2

5.6.4Products

5.6.4.1 The following minimum equipments shall be available:

a) Binocular Microscope
b) Chamber
c) Differential counter
d) Tally counter
e) Centrifuge
f) Timer
g) Refrigerator with thermometer
h) Test tube rack
i) ESR rack of five
j) ESR tubes
k) Spirit lamp
l) Slides,
m) Cover Slides,
n) Reagents,
o) Dry oven/ autoclave (can be shared with general clinic service)
p) Spectrophotometer (semi automated)
q) Shaker
r) Roller
s) Water bath
t) Chemistry machine(optional)
u) Glucometer
v) CBC machine

5.7 Radiography imaging services (Optional)

5.7.1Practice

5.7.1.1 The medium clinic may have X-Ray and ultrasound service.

5.7.1.2 The X-Ray service shall have written policies and procedures which shall include at least:

a)X-Ray Safety practices;

b)Management of the critically ill patient during imaging procedures;

c)Infection control, including patients in isolation;

d)Timeliness of the availability of diagnostic imaging procedures and the results;

e)Quality control program covering the inspection, maintenance, and calibration of all equipment.

5.7.1.3 There shall be a written protocol for managing medical emergencies in the radiological suite.

5.7.1.4 The X-Ray service unit shall be free of hazards to patients and personnel.

5.7.1.5 Proper safety precautions shall be maintained against fire and explosion hazards, electrical hazards, and radiation hazards.

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5.7.1.6 The Medium clinic shall post in easily accessible place all the necessary signs & the approval certificate from the Ethiopian Radiation Protection Authority through periodic inspection.

5.7.1.7 The medium clinic X-Ray unit shall keep documentation of the report for periodic readings of employee"s exposure for radiation by the use of exposure meters or badge tests.

5.7.1.8 The medium clinic shall make sure that the radiographer(s) put on personal TLD whenever on operating the radiation emitting machines.

5.7.1.9 Requests for X-Ray examination shall contain a concise statement of reason for the examination.

5.7.1.10 X-Ray results films shall be labeled with minimum information that includes: date, patient"s name, age, sex, location marks (L/R), name of institute and name of radiology professional /radiographer.

5.7.2 Premises

5.7.2.1 The X-Ray unit for medium clinic shall fulfill the design requirements of ERPA guidelines.

5.7.2.2 The premise for X-Ray service shall fulfill the ERPA requirements & be functional only if licensed/ certified by ERPA.

5.7.3 Professional

5.7.3.1 The medium clinic shall have a radiology professional/Radiographer.

5.7.4 Products

5.7.4.1 Imaging equipments which shall be available for x-Ray services at Medium clinic are indicated below:

a) x-ray machine,
b) Ultrasound machine
c) X-Ray viewing boxes,(optional)
d) Radiation protection equipments:
   - lead gloves,
   - lead apron
   - lead goggle,
   - gonad shields
e) Dark room film processing baths if necessary
f) Drier (optional),

5.7.4.2 The X-Ray machine shall be regularly inspected, maintained, and calibrated by licensed organ or ERPA; appropriate records of maintenance shall be maintained.

5.7.4.3 All radiation generating equipments shall be installed within a room/ building with wall thickness that protects radiation to the surroundings, i.e., the minimum criteria set by the Ethiopian Radiation Protection Authority / International Atomic Energy Agency (IAEA).

5.7.4.4 Installation and un-installation of radiation emitting machines like X-Ray shall follow the safety procedures set by the Ethiopian Radiation Protection Authority during all procedures.

5.8 Pharmacy Services

5.8.1 Practices

Dispensing and Medication Use Counseling

5.8.1.1 Standard operating procedure (SOP) for dispensing and medication use counseling shall be established to ensure patients" safety and correct use of medications.

5.8.1.2 Dispensers shall make sure that prescriptions are legible, written by authorized prescriber and complete. Prescription papers shall be standardized and must contain at least the following information and the prescriber shall complete all these information:

a) Name of patient, sex, age and medical record number,
b) Diagnosis and allergy, if any,
c) Name of the medicines, strength, dosage form, dose, frequency, and route of administration,
d) Duration of treatment,
e) Prescriber"s name, qualification and signature,
f) Prescriber"s address (name and address of Specialty center).

5.8.1.3 The pharmacy professional/level 4 pharmacy technician shall check the correctness of prescriptions in terms of appropriateness for patients and of dosage, strength and drug interactions based on approved standard treatment guidelines.

5.8.1.4 All medicines shall be dispensed with adequate and appropriate information and counseling to patients for correct use of their medications.

5.8.1.5 The pharmacy professional/level 4 pharmacy technician shall make an in-depth professional judgment to make sure that each medicines and its dosage form has all of its attributes of quality and an acceptable ratio of safety.

5.8.1.6 The containers used for dispensing shall be appropriate for the product dispensed and all containers intended for pharmaceuticals shall be protected and kept free from contamination, moisture and light.

5.8.1.7 All pharmaceuticals to be dispensed shall be labeled and the labels shall be unambiguous, clear, legible and indelible. The following minimum information shall be indicated on the label/ sticker:

a) the generic name of the product or each active ingredient, where applicable;
b) the strength, dose, frequency of administration and total quantity;
c) the name of the person for whom the medicines are dispensed;
d) the name of the prescriber and patient card number;
e) the directions for use and route of administration tailored to patient or caregiver literacy and language;
f) the name and business address of the dispenser;
g) date of dispensing; and
h) Special precautions as applicable

5.8.1.8 Filled prescriptions shall be signed and accountability must be accepted by the dispensing Pharmacist/druggist.

5.8.1.9 Each medium clinic shall establish and implement policies, guidelines and procedures for reporting any errors or any suspicion in administration or provision of prescribed medications. Errors shall be reported to the prescriber in a timely manner upon discovery and a written report of the error

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prepared and documented. Any suspicion or error shall be communicated to the prescriber and clarified/corrected before dispensing without affecting patient"s confidence on medical practices.

5.8.1.10 The pharmacy shall keep individualized information for patients with chronic illnesses medication program using standardized information tracking formats and update patient medication profile during each refill visit.

5.8.1.11 The responsible Pharmacist must ensure that patients are counseled before they receive pharmaceuticals that they are to self-administer.

5.8.1.12 Cautionary instructions and ancillary information about medications shall be communicated in writing to the personnel responsible for administering medications.

Control of Drug Abuse, Toxic or Dangerous Drugs

5.8.1.13 The medium clinic shall establish Policies and procedures to control the administration of psychotropic substances with specific reference to the duration of the order and the dosage in accordance with relevant laws.

5.8.1.14 A record of the stock on hand and of the dispensing of all these drugs shall be maintained in such a manner that the disposition of any particular item may be readily traced.

5.8.1.15 A licensed pharmacist/druggist shall dispense all controlled substances (psychotropic drugs) to the authorized health professional designated to handle controlled substances in the medium clinic. When the controlled substance is dispensed, the following information shall be recorded into the controlled substances (proof-of-use) record.

a) Name and signature of Pharmacist/druggist dispensing the controlled substance
b) Name and signature of designated licensed person receiving the controlled substance.
c) The date and time controlled substance is dispensed.
d) The name, the strength, and quantity of controlled substance dispensed.
e) The serial number assigned to that particular record, which corresponds to same number recorded in the pharmacy's dispensing record.

5.8.1.16 When the controlled substances are not in use, they shall be maintained in a securely locked, substantially constructed cabinet or area. All controlled substance storage cabinets shall be permanently affixed. Controlled substances removed from the controlled substance cabinet shall not be left unattended.

5.8.1.17 The administration of all controlled substances to patients shall be carefully recorded into the standard record for controlled substances and returned back to the Pharmacist/druggist upon refill of controlled substances. The following information shall be recorded during administration to patients.

a) The patient's name, card number
b) The name of the controlled substance and the dosage administered.
c) The date and time the controlled substance is administered.
d) The signature of the practitioner administering the controlled substance
e) The wastage of any controlled substance.

f) The balance of controlled substances remaining after the administration of any quantity of the controlled substance

g) Day-ending or shift-evening verification of count of balances of controlled substances remaining and controlling substances administered shall be accomplished by two (2) designated licensed persons whose signatures shall be affixed to a permanent record.

5.8.1.18 All partially used quantities of controlled substances shall be licensed in to the control substance record and returned back to the responsible pharmacy professional/level 4 pharmacy technician for control substances for disposal.

5.8.1.19 All unused and unopened quantities of controlled substances which have been removed from the controlled substance cabinet shall be returned to the cabinet by the practitioner at the end of each shift.

5.8.1.20 Any return of controlled substances to the pharmacy in the medium clinic shall be documented by licensed pharmacy professional/level 4 pharmacy technicians responsible for controlled substance handing in the medium clinic.

5.8.1.21 The medium clinic shall implement procedures whereby, on a periodic basis, a licensed pharmacy professional/level 4 pharmacy technicians shall reconcile quantities of controlled substances dispensed in the medium clinic against the controlled substance record. Any discrepancies shall be reported to the head of the clinic. Upon completion, all controlled substance records shall be returned to the pharmacy by the designated responsible person.

5.8.1.22 The clinic shall submit regular report to the appropriate organ regarding the consumption and stock of controlled drugs.

Adverse Drug Reactions/ Pharmacovigilance

5.8.1.23 The medicinal professionals shall identify patient suspected adverse drug reaction (ADRs), precaution, and contraindication during dispensing.

5.8.1.24 An adverse drug reaction reporting system shall be established to facilitate the detection of previously unknown or unpublished adverse effects, to permit the evaluation of factors that influence the safety and toxicity of medicines and promote the generation of statistics on the incidence of various adverse reactions to medicines. The responsible medicinal professional shall co-ordinate any adverse reaction.

5.8.1.25 Adverse drug reaction reporting shall be done in accordance with the guidelines for reporting adverse drug reactions in Ethiopia as published by EFDA.

Pharmaceutical Supply and Management

5.8.1.26 The pharmaceutical aspects of the purchase of all medicinal products and related materials shall be the responsibility of a technical manager.

5.8.1.27 The Medium Clinic shall purchase and dispense only Medium Community Pharmacy medicines list.

5.8.1.28 Due regard shall be paid to the storage conditions before purchase and to the labels, leaflets, appearance, origin and subsequent chain of supply of the medicine concerned.

5.8.1.29 The technical manager or officially delegated Druggist or pharmacist shall present to the supplier authenticated copy of the certificate of competence of the clinic"s Pharmacy for every purchase.

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5.8.1.30 The Medium clinic shall avail written policies for the procurement, storage, and dispensing of medicine and psychotropic substances.

5.8.1.31 The written policies shall assist in ensuring;

a) product availability ;

b) safety of medicines;

c) documentation of procurement and dispensing process ;

d) optimal storage conditions are monitored (including during transport);

e) effective inventory management;

f) Patients receive stock that has been suitably stored and has an expiry date that allows sufficient time for usage by the patient before the expiry date; and

g) Effective batch recall of medicines when necessary.

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

5.8.1.33 A technical manager or officially delegated druggist or pharmacist in charge shall not purchase any medicinal product where any doubt of safety, quality or efficacy.

5.8.1.34 Responsible medicinal professionals shall be satisfied that both the supplier and the source of any medicine purchased are trust worthy and recorded.

5.8.1.35 Quality assurance shall be an integral part of pharmaceutical practice.

5.8.1.36 Stock exchange or transfer shall not be done among Pharmacies without the permission of appropriate organ.

Good Dispensing Practice

5.8.1.37 A separate practice or business other than scope of practice shall not be permitted in the Pharmacy and the medicinal professionals shall implement systems of good dispensing practice.

5.8.1.38 The medicinal professionals shall ensure that dispensing occurs accurately, reflect the prescriber"s intention, and is consistent with the needs and safety of the consumer. The requisites here are:

a) The right patient gets the right medicine

b) Possible interactions are avoided.

c) The quality and integrity of the medicine are maintained throughout the indicated shelf life.

d) Correct and clear instructions are given to the patient to ensure correct and safe use of the medicine, to the optimal benefit of the patient in line with the objective of the treatment.

e) The patient is given, at the least, basic information regarding special instructions for use, warnings if applicable, possible adverse or side effect and action to taken in the event of certain events occurring.

5.8.1.39 The medicinal professionals shall obtain personal details and complete medication history from the patient and reviews.

5.8.1.40 The medicinal professionals shall contact the prescriber about a prescription or a patient"s therapy when necessary.

5.8.1.41 The medicinal professionals shall provide appropriate information to the patient to enable safe and effective use of the medicines and therapeutic device supplied.

5.8.1.42 Medicine shall not be removed from blister or foil packs at the time of dispensing, except in particular cases where repacking is required to assist patients.

5.8.1.43 Open or split packs shall be clearly marked, and mixing of stock of the same product from different batches avoided.

5.8.1.44 To minimize the incidence of a dispensing error occurring, similarly packaged medicine shall not be stored adjacent to each other on the dispensary shelf.

5.8.1.45 The medicinal professionals shall dispense medicines with legible and unambiguous labels.

5.8.1.46 A pharmacy professional/level 4 pharmacy technician is legally entitled to substitute generic medicine for brand name Products.

5.8.1.47 The pharmacy professional/level 4 pharmacy technician shall confirm legality, identifying the patient"s condition, legibility, and completeness of the prescription, correctness of the prescription, therapeutic aspects and appropriateness of the prescription paper.

5.8.1.48 The Medium Clinic shall have a standardized Prescription Registration Book (PRB) for recording every pharmaceutical issued to a patient.

5.8.1.49 A prescription monitoring service shall be established to ensure that both prescribing and dispensing of medicines are monitored regularly and to ensure compliance with accepted practice and safe systems of prescribing and dispensing.

Medicines Waste Management and Disposal

5.8.1.50 The disposal of medicine wastes shall be in compliance with the medicines waste management and disposal directives issued by EFDA.

5.8.1.51 The medium clinic pharmacy shall take responsibility, through supportive policies and procedures for the environmental and societal safety by efficiently managing the pharmaceutical wastes.

5.8.1.52 General wastes shall be collected daily from the pharmacy and placed in a convenient place outside the pharmacy to facilitate coordinated disposal by the clinic.

5.8.1.53 Solid wastes from the pharmacy shall be categorized as “hazardous” and „non-hazardous” and shall be collected separately for proper treatment.

5.8.1.54 Spillages of low toxicity shall be swept into a dust pan and placed into a suitable container for that particular chemical and dispose accordingly.

5.8.1.55 Medicines in single dose or single use containers which are open or which have broken seals, medicines in containers missing medicines source and exact identification (such as lot number), and outdated medications shall be collected to the pharmacy for disposal.

5.8.1.56 The clinic shall form a pharmaceutical waste disposal committee to ensure safety, accountability and transparency.

5.8.1.57 Disposal of pharmaceutical wastes shall be supported by proper documentation including the price, batch number & expiry date of the products for audit, regulatory or other legal requirements.

Recording

5.8.1.58 There shall be a standardized Prescription Registration Book for recording prescriptions and dispensed medicine.

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5.8.1.59 Each patient with a chronic disease shall have a separate Patients Medication Profile Card (PMP) that should be filled appropriately with all the relevant information for each patient.

5.8.1.60 Individual patient medicine records shall be maintained in a system, manual or Computerized, which allows for easy retrieval of patient information.

5.8.1.61 Psychotropic substances and their documents shall be kept in securely locked rooms or cupboards. The keys shall be kept in a secure place and it is preferable that only the technical manager of the pharmacy shall have access to them.

5.8.1.62 The prescription papers of patients shall be kept at least for three years. Whereas the prescription papers of psychotropic substances shall be kept at least for five years.

Billing

5.8.1.63 Medicine shall be received and issued using standard receiving and issuing vouchers. Receiving and issuing vouchers shall have the following minimum information.

a) generic name of medicines received and issued;
b) Unit of measurement and quantity and source (supplier"s or manufacturer"s name) of medicines;
c) Expiry date and batch number;
d) Unit and total price;
e) Date received and issued;
f) Name and signature of receiver and issuer; and
g) Address of the Pharmacy.

5.8.1.64 All medicine issued from the dispensary shall be dispensed/sold using standard Sales ticket with serial number registered by the appropriate finance bureau.

5.8.1.65 The Pharmacy shall use a standard stamp and seal for approving legal transactions.

5.8.2 Premises

5.8.2.1 The design and layout of the pharmacy shall permit a logical flow of work, effective communication and supervision and ensure effective cleaning and maintenance and must minimize the risk of errors, cross-contamination and anything else which would have an adverse effect on the quality of medicines and service delivery.

5.8.2.2 The area(s) of counseling shall be arranged or constructed in such a manner that it provides adequate space, have professional look and ensure reasonable privacy to the patient at all times and eliminate background noise as much as possible.

5.8.2.3 Dispensing counter &/ or counseling area shall be designed to secure patient privacy and confidentiality.

5.8.2.4 All parts of the pharmacy premises shall be maintained in an orderly and tidy condition.

5.8.2.5 Entrances, dispensing counters and doorways shall be accessible to persons with disability.

5.8.2.6 The dispensing environment (dispensing counter and counseling area) shall ensure confidentiality and allow simultaneous service delivery for multiple customers by multiple providers.

5.8.2.7 The ceiling height of the pharmacy store shall not be less than 2.6m. This height requirement shall increase depending on the climatic condition of the area

5.8.2.8 The wall and floor shall be constructed to protect the safety of pharmaceuticals from burglary, rodents, direct sunlight, moisture and others.

5.8.2.9 Medicines shall be shelved a minimum of 20cm above the floor, 1m wide between shelves and 50cm away from the wall and ceiling. If pallets are used, there shall be 20cm above the floor, one meter between pallets and 50cm away from the wall.

5.8.2.10 The pharmacy premises shall have the following minimum space or area.

a) Storage area
b) Dispensary area with counseling

5.8.3 Professional

5.8.3.1 The pharmacy service in the medium clinic shall be directed by a licensed Pharmacist

5.8.3.2 The dispensing of all prescriptions and medication use counseling shall be carried out by the pharmacy professional/level 4 pharmacy technician

5.8.3.3 The medium clinic shall have at least two licensed pharmacy professional/level 4 pharmacy technician.

5.8.3.4 The clinic shall have a pharmacy professional/level 4 pharmacy technician for the central medical store and inventory management.

5.8.3.5 The pharmacy service shall have support staff such as clerks, porters and cleaners.

5.8.4 Products

5.8.4.1 The pharmacy in the medium clinic shall have medicine lists within the framework of the national medicine list prepared by the regulatory authority.

5.8.4.2 There shall be adequate, suitable dispensing equipment in the dispensary.

5.8.4.3 The medium clinic shall have central medical store equipped with fire extinguisher, refrigerators, and racks/shelves.

5.8.4.4 The medium clinic pharmacy shall be provided with continuous supply of electricity, telephone access.

5.8.4.5 The medium clinic Pharmacy shall have at least the following equipment;

a) Counting tray and tablet cutter
b) A refrigerator equipped with calibrated thermometer
c) Dispensing containers
d) Shelf
e) Separate secured cabinets with lock and key for keeping psychotropic medicines
f) Regularly calibrated wall thermometer and hygrometer or thermo hygrometer
g) Ventilator or air conditioner as appropriate.
h) Fire extinguisher.
i) Scientific Calculator, scissor, and fixed line telephone.

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INSTITUTE OF ETHIOPIAN STANDARDS

Organization and Objectives

The Institute of Ethiopian Standards (IES) is the national standards body of Ethiopia. IES is re-named by the proclamation number 1263/2021, from Ethiopian Standards Agency (ESA) to Institute of Ethiopian standards, with the mandate given by the regulation Number, 193/2010 and proclamation number, 1263/2021.

IES's objectives are:

- Develop Ethiopian standards and establish a system that enable to check whether goods and service are in compliance with the required standards,
- Facilitate the country's technology transfer through the use of standards,
- Develop national standards for local products and services so as to make them competitive in the international market.
- Conduct standards related research and provide training and technical support.

Ethiopian Standards

The Ethiopian Standards are developed by national technical committees which are composed of different stakeholders consisting of educational and research institutes, governmental organizations, certification, inspection, and testing organizations, regulatory bodies, consumer association etc. The requirements and/ or recommendations contained in Ethiopian Standards are consensus based that reflects the interest of the TC representatives and also of comments received from the public and other sources. Ethiopian Standards are approved by the National Standardization Council and are kept under continuous review after publication and updated regularly to take account of latest scientific and technological changes.

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