

**CES 188**

# **Compulsory Ethiopian Standard**

Second Edition  
xx-xx-2024

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## **Primary clinic in organization**

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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 188:2018, Primary clinic in organization .

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.

# Primary clinic in organization

## 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 primary clinic.

This requirement is applicable for all new and existing primary 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.

## 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 primary 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 who have primary clinic to deliver service for the staff and/or the staff's families without any price.

### 3.8

#### **primary clinic**

the next level to primary level of the healthcare in ambulatory health service that provide mainly curative service and preventive and promotive services indicated in this requirement.

### 3.9

#### **initial licensure**

the process of providing/ obtaining a License to operate a new or upgraded Primary clinic

## 4. Service requirements

### 4.1 General outpatient Medical Practices:

#### 4.1.1 Practices

**4.1.1.1** The primary clinic shall provide outpatient care (diagnosis & treatment) for ambulatory patients & treatment of acute conditions.

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

**4.1.1.3** Preventive and health promotive services for patients attending the clinic.

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

**4.1.1.5** 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°, Pain assessment) and weight
  - **Physical** examination pertinent to the illness

c) Diagnostics impression

**d) Rapid test(optional) (RBS.RDT,HCG)**

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

**4.1.1.7** The primary clinic shall have clinical protocols for management of at least common disease entities like malaria, hypertension and locally significant diseases.

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

**4.1.1.9** 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

**4.1.1.10** Nursing procedures:

- a) Administration of Injection with prescription (Prescribed medicines),
- b) Change Dressing with prescription and application of simple dressing,
- c) Taking Vital sign,
- d) Enema with prescription,
- e) Ear irrigation simple foreign body removal following otoscopy,
- f) Counseling and Referral of suspected/ potential STI, TB, HIV and other conditions
- g) Treatment of mild to moderate dehydration and referral of severe dehydration cases

- h) Resuscitation including iv fluid administration
- i) Catheterizations
- j) Immobilization

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

**4.1.1.12** The services rendered at the primary clinic shall comply with the requirements prescribed under patient rights and responsibilities requirement.

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

## **4.2 Emergency service**

### **4.2.1 Practices**

**4.2.1.1** The emergency service shall be available during the organizational working hours.

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

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

**4.2.1.4** The emergency service shall provide basic life support as indicated for any emergency cases, which includes at least the followings :

- a) Airway management,
- b) Bleeding control
- c) Fluid resuscitation
- d) Cardiopulmonary resuscitation (CPR)
- e) Immobilization
- f) NG tube insertion

**4.2.1.5** 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.

**4.2.1.6** There shall be Protocols for initial management of at least for the following emergency cases:

- |                             |  |
|-----------------------------|--|
| a) Shock                    | i) Acute diarrhea ( Severe dehydration ) |
| b) Severe Bleeding          | j) Acute abdomen                         |
| c) Fracture and injuries    | k) Tetanus                               |
| d) Coma                     | l) Meningitis                            |
| e) Burn                     | m) Severe & complicated malaria          |
| f) Poisoning                |  |
| g) Seizure disorder         |  |
| h) Hypertension emergencies |  |

- 4.2.1.7 Infection prevention requirements shall be implemented in the emergency/ procedure room as per the IPC guideline.
- 4.2.1.8 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.
- 4.2.1.9 If the patient to be referred needs to be attended by a health professional during the transfer process, the Primary clinic has the responsibility of assigning the accompanying professional.
- 4.2.1.10 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
- 4.2.1.11 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.

**4.2.2 Premise**

The Primary clinic shall have:

- 4.2.2.1 Direct access to examination room for emergency,
- 4.2.2.2 Hand washing basin/ facility at examination and treatment room,
- 4.2.2.3 Cabinet/ cup board with lock for equipments and supplies,
- 4.2.2.4 Staff changing corridor or room with cabinet, chairs, cupboard.
- 4.2.2.5 The facility shall maintain privacy and be friendly for persons with disability.
- 4.2.2.6 There shall be a note in visually accessible area that details the facilities working hours and list of services available in the facility.
- 4.2.2.7 The primary clinic shall have a minimum of the following premises set up:

**Table 1- Premises required for the clinic**

Premises required	Number	Area required
Reception, Registry/ Recording & Waiting area	1	12 sq. m
Examination room	1	12 sq. m
Treatment/ procedure/ injection room,	1	12 sq. m
Emergency resuscitation room with two beds	1	16 sq. m
Instrument processing room or area	1	6sq. m
Toilet (Gender specific)	2	
Incinerator (mobile/ fixed)	1	
Placenta pit (optional)		

**4.2.3 Professionals**

- 4.2.3.1 The primary clinic shall be directed by a licensed BSc nurse or Health officer.
- 4.2.3.2 The primary clinic service shall be limited to the scope of practice in the clinic.
- 4.2.3.3 The primary clinic shall have at a minimum the following staff:

**Table 2- Professionals required for the clinic**

Staffs required	Number required
BSc nurse/HO	1
Nurses(clinical/ BSc)	1
Receptionist	1
Cleaner	1

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

#### **4.2.4 Products**

**4.2.4.1** Primary clinic shall have the following equipments and supplies:

a) Equipments :

- Stethoscope,
- Thermometer(digital/mercury),
- BP apparatus (sphygmomanometer with stethoscope),
- Measuring tape,
- Weighing scale
- Otoscope
- Glucometer,
- Examination light,
- Dressing set,
- Minor suturing set,
- Enema set,
- Kidney basin,
- Plastic apron,
- Drapes/ Rubber sheets,
- Suction machine
- Suction ball (optional),
- Waste basket,
- Sharp disposal boxes,
- Pickup forceps with jar,
- Sterilizer (steam autoclave/ hot air oven)
- Examination couch,
- Fetoscope
- IV stand,
- Resuscitation equipments
- Pulseoxymetry
- Storage shelves for the medical equipment, medicines and supplies
- Recording and Reporting materials
- first Aid kit,
- oxygen cylinder with nasal prong and flow meters

b) Consumables:

- Disposable glove
- Surgical glove
- Alcohol/ Iodine/
- PPE
- Gauze
- Bandage,
- Cotton
- IV Cannulae
- Adhesive tape,
- Surgical blades
- Tongue depressor,
- Splints (locally produced/ adapted),
- Foley Catheters,
- Suturing materials
- NG tube
- Tourniquets
- KY jelly
- Dressing packs
- Steri-strips for steam autoclave
- Disinfectant chemicals (Bleach)
- Disposable syringe with needle

**4.2.4.2** Emergency medicines allowed for primary clinic as per emergency medicine list prepared by EFDA.

## Bibliography

Ethiopian Food, medicine and Healthcare Administration and Control Proclamation No. 661/2009

Ethiopian Food, Medicine and Healthcare Administration and Control Regulation No. 189/2010

Health Policy of Ethiopia

Drug Policy of Ethiopia

Commercial Code of Ethiopia

Criminal Code of Ethiopia

Medicines Waste Management and Disposal Directive No 2/2011

Ethiopian National Guideline for Health Waste Management, 2008

Ethiopian Building Proclamation, No. 624/2009

## 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.

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