

Standard No.CEA/Clinic- 009

**Clinical Establishment
Act Standard for
Clinic / Polyclinic with
Dispensary**

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Introduction

In 2010 Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Central Government to provide for registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them.

The Ministry has notified the “National Council for Clinical Establishments” and ‘The Clinical Establishments (Central Government) Rules, 2012” under this Act vide Gazette. *This Act is applicable to all kinds of clinical establishments from the public and private sectors, of all recognized systems of medicine including single doctor clinics. The only exception will be establishments run by the Armed forces.*

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Clinic/ Polyclinic with Dispensary

1. Definition

- 1.1 A clinic may be defined as a clinical establishment providing examination, consultation, prescription to outpatients including dispensing of medicines by a single / general practitioner/ specialist doctor /super-specialist doctor.
- 1.2 A polyclinic may be defined as a clinical establishment providing examination, consultation, prescription to outpatients including dispensing of medicines by more than one doctor/ general practitioner/ specialist doctor /super-specialist doctor.
- 1.3 A few minor procedures like dressing and administering injections etc may be provided in the clinic/polyclinic however not requiring observation/short stay.
- 1.4 Dispensing of medicines shall be done by qualified professionals to out patients.

2. Scope (as applicable)

- 2.1 These set of common minimum standards framed are applicable to a single practitioner/more than one doctor clinic manned by a General physician/ specialist doctor/super specialist or a group of doctors who are themselves providing patient care services like dispensing of medicines, injection and dressing.
- 2.2 To provide examination, consultation, prescription to outpatients by a single doctor/ general physician / specialist doctors /super-specialist doctor or group of doctors who are themselves providing patient care services like dispensing of medicines, injection and dressing.
- 2.3 To deliver primary service in health education and health promotion;
- 2.4 To deliver health care services of rehabilitative nature.
- 2.5 **Any or more than one of the following are included:**
 - a) Gen Physician
 - b) Cardiology
 - c) Cardiothoracic surgery
 - d) Dermatology
 - e) ENT

- f) Endocrinology
- g) Gastroenterology
- h) Internal Medicine
- i) Gen Surgery
- j) GI –Surgery
- k) Gynecology & Obstetrics
- l) Medical/Surgical Oncology
- m) Nephrology
- n) Neurosurgery
- o) Neurology
- p) Ophthalmology
- q) Orthopedics
- r) Pediatrics/pediatric surgery
- s) Psychiatry
- t) Rheumatology
- u) Thoracic surgery
- v) Tuberculosis and Respiratory Disease
- w) Urology

3. Infrastructure

- 3.1 The physical facility shall be developed and maintained to provide safe and secure environment for patients, their families, staff and visitors. It shall be situated in a place having clean surroundings and shall comply with local byelaws in force, if any from time to time.
- 3.2 The minimum space requirement for carrying out the basic functions of the facility shall be as per Annexure 1.
- 3.3 The area shall be well illuminated, ventilated and clean with adequate water supply.
- 3.4 The clinic shall have a prominent board/signage displaying the name of the clinic in local language at the gate or on the building of the clinic.
- 3.5 The following other signage shall be well displayed in the language understood by the local public in the area:
 - a) Name of the doctors with registration number.
 - b) Fee structure of the various doctors/ specialist
 - c) Timings of the clinics (For ex – from 8am -2pm)

- d) Services provided within the Facility

4. Furniture & Fixtures

- 4.1 Furniture and fixtures shall be available in accordance with the activities and workload of the Clinic/polyclinic.
- 4.2 The furniture and fixtures shall be functional all the time. For indicative list of items refer to Annexure 2 (this list is indicative and not exhaustive).

5. Human Resource Requirements

- 5.1 The general practitioner/ specialist doctor /super-specialist doctors as per the scope of the clinic/polyclinic shall be registered with State/Central Medical Council of India.
- 5.2 The services provided by the medical professionals shall be in consonance with their qualification, training, registration.
- 5.3 If dispensing is done by Paramedic like pharmacist, he shall be qualified, trained and registered with pharmacy council.

6. Equipment/instruments/drugs

- 6.1 The clinic/polyclinic shall have essential equipments as per Annexure 3 and emergency equipment as per Annexure 4.
- 6.2 Other equipments as per the scope of service being practiced shall also be available.
- 6.3 Adequate space for storage of equipments and medicines shall be provided and if available medicines shall be stored as per manufacturer's guidelines. The equipment shall be of adequate capacity to meet work load requirement.
- 6.4 All equipment shall be in good working condition at all times. Periodic inspection, cleaning, maintenance of equipment shall be done.
- 6.5 The clinic/polyclinic shall have basic minimal essential drugs as per Annexure 6, however other drugs as per the scope of service being practiced may also be available.

7. Support Service

7.1 In a Clinic/polyclinic minimum one support staff must be available to meet the care treatment and service needs of the patient. However number may depend upon the workload and scope of the service being provided by the clinical establishment.

8. Legal/Statutory Requirements

S. No	Name of the Act/License	Department/Area	Licensing body
1	Registration of medical doctor with Central/State Medical Council	Administration	MCI/State Medical Council
2	Biomedical Management & Handling Rules, 1998	Administration	State pollution control Board
3	Local registration of the Clinic	Administration	State Council
4.	Pharmacy License	Administration	Indian Pharmacy Council

9. Record Maintenance and reporting

9.1 Every Clinical Establishment shall maintain medical records of patients treated by it and health information and statistics in respect of national programmes and furnish the same to the district authorities in form of quarterly reports.

9.2 Copies of all records and statistics shall be kept with the clinical establishment concerned for at least 3 or 5 years or in accordance with any other relevant Act in force at the time under Section 12(1) (iii) of CEA 2010).

9.3 All clinical establishments shall be responsible for submission of information and statistics in time of emergency or disaster or epidemic situation or as required from time to time by National Council CEA 2010.

9.4 Medicine Records and Registers

10. Basic processes

10.1 Registration

10.1.1 Every patient visiting the clinic shall be registered.

10.2 Assessment

10.2.1 Every patient shall undergo assessment, during the course of assessment, the patient findings, medications and investigations should be documented with working diagnosis, legibly in the assessment/OPD prescription with the signature of the consultant/ Specialist / super Specialist with date and time.

10.2.2 The Medicine shall be dispensed by qualified doctor or pharmacist as allowed by law.

10.2.3 No medicines shall be dispensed from pharmacy store without a written prescription order of doctor, except in emergency cases. Medication dispensing shall be done with care to prevent any medication error. Following shall be checked before dispensing of medication. These checks shall be done at store level.

10.2.3.1 Medicine prescribed.

10.2.3.2 Dose of prescribed medicine.

10.2.3.3 Expiry date.

10.2.3.4 Particulate matter in liquid dosage forms and parenteral drugs.

10.2.3.5 Labels (if reconstituted drugs).

10.2.4 Labelling shall be done for every prepared / reconstituted medication, which shall include name, date of preparation, strength and frequency of administration of drug.

10.3 Infection Control

10.3.1 The clinic shall take all precautions to control infections like practicing hand hygiene etc.

10.3.2 The clinic shall have availability of clean water for hand washing /liberal use of sanitizer should be maintained throughout the working hours of the clinic.

10.3.3 Sanitation and hygiene of the toilets if available shall be maintained.

10.3.4 Mopping of all patient care areas with disinfectant shall be done at least once a day

10.4 Safety Considerations

10.4.1 Effort shall be made to take care of patient safety aspects like patient fall, etc.

10.4.2 Effort shall be made to keep clinic pest and termite free.

10.5 Biomedical waste Management

10.5.1 Biomedical waste should be managed in accordance with the BMW management and handling Rules, 1998.

10.5.2 Clinic waste generated should be segregated at source.

10.5.3 Needles and sharp waste should be stored in puncture proof container

10.6 First aid

10.6 Provision shall be made for providing First Aid.

10.7 Contact details of ambulance hospital etc shall be available.

Annexure 1
Infrastructure requirement

Minimum area required for a clinic:

clinic	COMMON AREA		Consultation room Ancillary area/space	Remarks
	Reception	Waiting		
	35 sqft carpet area		70 sqft carpet area including storage	Area specified under consultation room is only for single clinic and shall be multiplied accordingly by the number of consultation chambers.
			40 sq.ft	Store and Pharmacy

Note: Reception, waiting, consultation room etc shall be adequate as per the requirement and workload of the clinic.

Ancillary area/space: Storage of records, reagents, consumables, stationary etc and eating area for staff

Annexure 2Furniture/fixtures

S.N.	Articles
1.	Table
2.	Chairs
3.	Examination Table/couch
4.	Screens
5.	Foot Step
6.	Stools
7.	Storage Cabinet for records etc.
8.	BMW storage area

Annexure- 3**I. Essential Equipment:**

S. No.	Name of the equipment	Minimum Specifications	No. of equipment
1	Stethoscope		1
2	Thermometer	Digital	1
3	Torch (flash lights)		1
4	Sphygmomanometer(B.P. Apparatus)	Digital	1
5	Weighing machine(Optional)	Adult	1

Annexure- 4**I. Emergency Equipment:**

S. No.	Name of the equipment	Minimum Specifications	No. of equipment
1	Resuscitation Equipment	- Adult	1
	Ambu Bag/Air Way	- Pediatric	1
2	Oxygen Concentrator/ Cylinder (Portable)		1
3	Fire Extinguisher	-	1

Annexure- 5**I. Emergency Drugs**

S. No.	Name of the Drug	Minimum Quantity
1	Inj Adrenaline	2 A
2	Inj Hydrocortisone	1 vial
3	Inj Atropine	1 Ampoule
5	InjAvil	1 Ampoule
6	InjPhenargan	1 Ampoule
7	Inj. Deryphyline	1 Ampoule
8	Inj. Frusemide	1 Ampoule
9	Inj. Metoclopramide	1 Ampoule
10	Inj. Dexamethasone	1 Ampoule
11	Inj. Diazepam	1 Ampoule
12	Inj. Dicyclomine Hydrochloride	1 Ampoule
13	Inj. 5% dextrose infusion	1 Vac
14	Inj. Normal saline	1 Vac

Glossary

1. **General Physician:**M.B.B.S doctor who attend to the medical needs of individuals within a community.
2. **Ancillary area/Ancillary space:** The nonpublic areas or spaces of the stations usually used to house or contain operating, maintenance, or support equipment and functions
3. **Support Staff:** The staff, who support the patient care services provided in a clinical establishment.
4. **First Aid:**First aid is a provision of initial care given to a victim of an injury or sudden illness.