

What Is Clinical establishment Act?

- This bill makes it mandatory for each and every clinical establishment including every individual clinic, consulting chamber, laboratory or any other investigative or treatment place without indoor beds, nursing homes, hospital etc. by whatever name it may be called to register and follow minimum standards of infrastructure i.e. of space / equipment and qualified para medical staff.

- It provides for mandatory registration of all clinical establishments, including diagnostic centers and
- single-doctor clinics across all recognized systems of medicine both in the public and private sector
- except those run by the Defense forces

Introduction

- The Clinical Establishments Act was passed by Parliament of India on **17th August 2010**
- The Act was notified vide Gazette notification dated **28th February, 2012.**
- The Ministry of Health and Family Welfare has notified the National **Council** for Clinical Establishments and the Clinical Establishments (Central Government) **Rules, 2012** under this Act vide Gazette notifications dated 19th **March, 2012** and 23rd **May, 2012** respectively.
- NSSO estimates, as much as 40% of the private care is likely being provided by informal unqualified providers.

Definition



THE CLINICAL ESTABLISHMENT (REGISTRATION AND REGULATION) ACT, 2010

- Clinical establishments defined as health care establishments by any name, engaged in diagnosis, treatment or care of injury, illness, pregnancy, disability, or abnormality.
 - a clinical establishment owned, controlled or managed by a Government or
 - a) department of the Government;
 - b) a trust, whether public or private;
 - c) a corporation (including a society) registered under a Central, Provincial or State Act, whether or not owned by the Government;
 - d) a local authority; and
 - e) a single doctor
- (**Exception:** establishments of the Armed Forces)

Objectives of the Act



- To establish **digital registry of Clinical Establishments at National, State and District level.**
- To prevent **quackery by unqualified practitioners by introducing** registration system, which is mandatory.
- To improve quality of health care through standardization of healthcare facilities by prescribing **minimum standards of facilities and services for all categories of health care establishments.**

Authority



National Council for clinical establishments

- DGHS, Ex-officio, **Chairperson**
 - 4 elected representatives, out of which
 - Medical Council of India (**one representative**),
 - Dental Council of India (**one representative**),
 - Nursing Council of India (**one representative**),
 - Pharmacy Council of India(**one representative**),
 - Indian Medicines representing the Ayurveda,Siddha,Unani (**three elected representatives**),
 - Central Council of Homoeopathy (**one elected representative**) ,
 - Indian Medical Association (**one elected representative**),
 - Bureau of Indian Standards (**one representative**),
 - Association of Indian Systems of Medicines relating to Ayurveda, Siddha,Unani to be nominated by the Central Government (**one representative**)
 - Secretary General of the Quality Council of India,
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AT DISTRICT LEVEL

- **District Registering Authority**
- Chairman: District collector/District Magistrate (DM)
- Convener: Joint Director Health Services JDHS
- Three members: to be nominated by DM
 - a) City Police Commissioner/SSP/SP or nominee
 - b) Senior officer of local self Government at district level/ DDHS/MHO/CHO
 - c) Professional medical Association/body IMA,IAP

Powers & Responsibilities:



- a) Grant/Renew provisional (within 10 days)/permanent registration.
- b) List expired Registrations.
- c) May **issue a notice to Clinical Establishment** to show cause within 3 months, if condition(s) of registration are not met
- d) To **enter and search unregistered CE** (after due notice), inspection and inquiry of registered Clinical establishments
- e) **May cancel registration** (after giving reasonable opportunity) and giving reasons After cancelling registration, immediately restrain Clinical Establishment if imminent danger to the health and safety of patients
- f) Recover **penalties**
- g) **Maintain District register** of Clinical establishments

Minimum required standards

- **Clinic / Polyclinic only Consultation (level 1A)**
space :



Common area		Consultation area
Reception	Waiting	Room
35 sqft	35 sqft	70 sqft

Human Resource:

One Doctor – MBBS / BDS registered in any MCI

One Support staff – registered in any nursing council

Furniture/fixtures

S.NO	Articles
1	Table
2	Chairs
3	Examination Table/couch
4	Screens
5	Foot Step
6	Stools
7	Storage Cabinet for records
8	BMW storage area

Essential Equipment

Equipment	Minimum specification	Number
Stethoscope		1
Thermometer	Digital	1
Torch (flash lights)		1
Sphygmomanometer(B.P. Apparatus)	Digital	1
Weighing machine(Optional)	Adult	1

Emergency Equipment

Equipment	Minimum specification	Number
Resuscitation Equipment Ambu Bag/Air Way	Adult Pediatric	1 1
Oxygen Concentrator/ Cylinder .	Portable	1
Fire Extinguisher		1

Emergency Drugs

Name of the Drug	No of ampule
Inj Adrenaline	2 A
Inj Hydrocortisone	1 vial
Inj Atropine	1 Ampoule
Inj Avil	1 Ampoule
Inj Phenargan	1 Ampoule
Inj. Deryphyline	1 Ampoule
Inj. Frusemide	1 Ampoule
Inj. Metoclopramide	1 Ampoule

Emergency Drugs

Name of the Drug	No of ampule
Inj. Dexamethasone	2 A
Inj. Diazepam	1 vial
Inj. Dicyclomine Hydrochloride	1 Ampoule
Inj. 5% dextrose infusion	1 Vac
Inj. Normal saline	1 Vac

Penalties under the Act



Offences	penalties		
	FIRST ATTEMPT	SECOND ATTEMPT	SUBSEQUENT ATTEMPT
Running Clinical Establishment without registration	50,000	2,00,000	5,00,000
Contravention of any other provision of the Act	10,000	50,000	5,00,000
Whoever knowingly serves in an unregistered Clinical Establishment	25,000		
Minor deficiencies which do not pose imminent danger	10,000		