

## Clinical Establishment Act: A Review

### Abstract:

The Clinical Establishments (Registration and Regulation) Bill 2007 reiterates the concerns of the Working Group in its statement of objects and reasons. This is an Act that is proposed to be brought into force to streamline the functioning and provision of services by clinical establishments. Importantly, it is a matter that regulates not just allopathic facilities, but also clinical establishments that provide services in a range of Indian systems of medicine. The relevance of this enactment lies in the fact that there has been an increasing concern about the gross inadequacy of public health facilities on the one side and the lack of any standards to regulate the existing facilities – both public and private – on the other.

**Key-words:** .....

### Introduction:

**The Clinical Establishments Act** was passed by Parliament of India on 17th August 2010, to provide for registration and regulation of all clinical establishments in the country with a view to prescribing minimum standards of facilities and services which may be provided by them so that mandate of article 47 of the constitution for improvement in public health may be achieved. . The Act was notified vide Gazette notification dated 28th February, 2012 and initially came into force on 1st March, 2012 in the four states namely: Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim and all Union Territories except Delhi. Further the states of Uttar Pradesh, Rajasthan, Bihar, Jharkhand, Uttarakhand and Assam adopted the Act under clause (1) of article 252 of the Constitution. At present, the Act is applicable in aforesaid 10 states and 6 Union Territories. The Act is applicable to all kinds of clinical establishments from public and private sectors, of all recognized systems of medicine including single doctor clinics. The only exception is establishments run by the Armed forces which will not be regulated under this Act.

### Clinical establishments not covered under the Act are:

- Clinical establishments owned, controlled or managed by the Armed Forces.
- Clinical Establishment in the States /UTs mentioned in the schedule of the Act; unless they repeal existing Act and adopt Clinical Establishments Act.
- Also, Clinical Establishments of those categories and of those recognised systems of medicine for which date has not been appointed by the State Government, who has otherwise adopted the Act.


**Clinical Establishments Act** aims to register and regulate clinical establishments based on minimum standards in order to improve quality of public health care in the country.

<sup>1</sup>VAIBHAV TANDON, <sup>2</sup>DIYA KUMARI

<sup>1-2</sup>Department Of Public Health Dentistry  
Kothiwal Dental College & Research Centre  
Moradabad

**Address for Correspondence:** Dr. Vaibhav Tandon  
Department Of Public Health Dentistry Kothiwal  
Dental College & Research Centre, Moradabad  
Email :vaibhavtandon35@gmail.com

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**The specific objectives are:**

- 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 (except teaching hospitals,) and ensuring compliance of other conditions of registration like compliance to standard treatment guidelines, stabilization of emergency medical condition, display of range of rates to be charged, maintenance of records etc.

**Registration Procedure of Clinical Establishments**

Registration application is in English (online and offline) OR Hindi (offline only). There are two types of registration — provisional and permanent and can be done in following ways:

- In person
- By post
- Online

If an application is being made **in person or by post** then it can be sent in the prescribed pro forma along with prescribed fee to be made to district registering authority (i.e. District Health Officer / Chief Medical Officer of district concerned).

**Provisional Registration:**

The clinical establishment is expected to apply for provisional registration initially. However after notification of minimum standards, the clinical establishment may apply for direct permanent registration also. For purpose of provisional registration, an application form in the prescribed proforma along with the prescribed fee as determined by the State Government will be required.

**No Inspection or Enquiry for Provisional Registration:**

For provisional registration, the authority shall not undertake any inspection or make any enquiry prior to the grant of provisional registration and shall within a period of ten days

from the date of receipt of such application, grant to the applicant a certificate of provisional registration containing particulars and information as per **format of certificate of provisional registration** either by post or electronically under Section 15, read with Section 17 of the Act.

**Validity of provisional registration:**

Every provisional registration shall be valid to the last day of the twelfth month from the date of issue of the certificate of registration and such registration shall be renewable.

**Renewal of provisional registration:**

The application for renewal of registration shall be made to the authority within **thirty days** before the expiry of the validity of the certificate of provisional registration. In case the application for renewal is made after the expiry of the provisional registration, the authority shall allow renewal of registration on payment of such enhanced fees, as may be prescribed by State Government.

**Permanent Registration:**

A clinical establishment, applying for permanent registration, has to submit **evidence of** it having complied with the prescribed minimum standard.

After commencement of permanent registration, provisional registration will NOT be granted or renewed beyond:

- Period of two years from the date of notification of the standards in case of clinical establishments which came into existence after the commencement of this Act but before the notification of the standards.
- Period of six months from the date of notification of the standards, for clinical establishments which came into existence after standards have been notified.

**Inspection:**

The registering authority may authorize an inspection or an inquiry of any registered clinical establishment to be made by a **multi-member inspection team**. A **show cause notice** may be issued if the authority feels that a clinical establishment is not complying with the conditions of its registration. It may also **cancel** the registration. The authority may **enter and**

**search** in the prescribed **manner after giving notice** of its intention to the clinical establishment, if it suspects that an establishment is operating without registration. Information pertaining to compliance with standards and conditions of registration by clinical establishments is to be displayed in the public domain. If there are objections about the authenticity of the information, this would be duly investigated by the Registering Authority. Any person, aggrieved by an order of the registering authority, refusing to grant or renew a certificate of registration or revoking a certificate of registration may, in such manner and within such period as may be prescribed, can refer an appeal to the State Council.

**Validity of permanent registration:** Every **permanent** registration shall be valid for a period of five years from the date of issue of the certificate of registration and such registration shall be renewable.

**Renewal of permanent registration:** The application for **renewal of permanent registration** shall be made six months before the expiry of the validity of the certificate of permanent registration and, in case the application of renewal is not submitted within the stipulated period, the authority may allow renewal of registration on payment of such enhanced fees and penalties as may be prescribed.

**Minimal standards for dental clinic**

Indicative minimum space requirements for a dental hospital/centre shall be as follows (These are indicative minimum figures, actual size will depend on scope of services of the hospital):

Space Area for one dental Chair	Includes Common and Operatory Areas	100 Sq ft/single chair Dental unit
<b>Common area</b>	Space for reception, waiting area, toilets etc.	35 sq ft
<b>Operatory</b>	Dental Chair unit including washing area and bio medical waste	60 sq ft carpet area for 1 dental chair
	Ancillary area/space for sterilization, dark room, storage, provision of compressed air and suction sterilization	30% of the carpet area for 1 dental chair

There should be adequate space between two dental units enough for patient privacy, ease of movement of staff and proper sanitization

**Essential Equipment List For Primary Oral Health Delivery And Checking Vital Parameters:**

- Equipments:** Dental chair with attachments like air motor/air rotor/micro motor, autoclave, compressor, stethoscope, sphygmomanometer, suction unit, oxygen cylinder with ambu bag.
- Essential instrument list:** BP blade , cotton, suture , hypodermic needles -disposable , saline solution , burs, gloves, masks, potable water, disinfectant(general cleaning ), disinfectant (instruments), lubricating oil for hand pieces, soap, surgical spirit.
- Periodontology:** Periodontal probe, scalers, curesttes.
- Oral Medicine and Radiology :** X-ray films, X-ray film developer – manual/automatic processing, X-ray film fixer - manual/automatic processing (If digital radiography available in the clinic, the above are optional)
- Oral surgery:** Elevators (various), forceps, needle holder, scissors–surgical, BP blade and handle.
- Conservative Dentistry:** Filling instruments, cement spatula (metal/plastic), waste receiver, dental hand pieces, excavators, explorers, glass slab/paper mixing pad, matrix retainer, protective glasses, cellophane strip.
- Endodontic:** Endo root canal explorer, plugger, spreader, ruler, spirit lamp or similar instrument for heating purpose.
- Prosthodontics:** Impression trays, rubber bowl, ruler scale, spatula, carver, shade guide, finishing and polishing instruments (e.g acrylic trimmer, etc), wax knife, wax spatula, cement spatula (metal/plastic), waste receiver, dental hand pieces, pliers, glass slab/paper mixing pad, spirit lamp or similar instrument for heating purpose.
- Orthodontics:** Pliers, applicable armamentarium.
- Pedodontics:** Fluoride, pit and fissure sealant, zinc oxide and eugenol, calcium hydroxide
- Implant Dentistry:** Implants with surgical kit, physio dispenser, other surgical instruments

**Essential Emergency Drugs:**

Oxygen, Epinephrine, Atropine, Ephedrine, Hydrocortisone, Nitroglycerine, Antihistamine (diphenhydramine or chlorphenramine), Albuterol/Salbutamol, Lorazepam, Ethamsylate, Hemostat sponge, Glucose / dextrose-25% ampoule.

Minimum Human Resource for Dental Hospitals shall be as follows

Sl. no.	Category	Strength	Registration with the concerned council (If applicable)
1.	Dentist	1	State Dental council
2.	Dental Hygienist	Depending on the work load	State Dental council
3.	Dental Assistant / Auxillary	Depending on the - work load	
4.	Dental technician	Depending on the work load	State Dental council
6.	Others	There should be provision of an on call Anesthetist, General Physician, General Surgeon as and when required	

**Conclusion:**

**As per the Clinical Establishment Act 2010,**

1. The Government will fix all the charges that can be charged for any procedure by a doctor or the Hospital including the consultation fees of the doctor. In this case the doctors will have to provide bill to the patients for the consultation fees and will have to account the same even in the outpatient clinics. Also the copy of the prescription should be sent to the authority regularly.

2. The patients have to be stabilized before transfer as per the clinical establishment act 2010.

If not stabilized properly the blame will be only on the Doctors.

3. During the irregular period, from the date expiry of validity of the registration to the time of issue of new one, can be three months as per the act; the practitioners have to close down the institution or stop practicing.

**References:**

1. Kasimi K. Indian Medical Association disapproves Clinical Establishment e Bill. *Top News* [Internet]. Arab Emirates. 2010 Jun 30 [cited 2010 Sep 27]. Available from: <http://topnews.ae/content/22653-indian-medical-association-disapproves-clinical-establishment-bill>
2. Express News Service. IMA doctors against Clinical Establishments Bill. *Indian Express* [Internet]. 2010 Feb 9 [cited 2010 Sep 27]. Available from: <http://www.indianexpress.com/news/ima-doctors-against-clinical-establishment-b/576939/>
3. IMA opposes Clinical Establishment Bill. *Zeenews.com* [Internet]. 2010 Jul 16 [cited 2010 Sep 23]. Available from: <http://www.zeenews.com/news641303.html>
4. Parmar RS. Memorandum: IMA to observe Punjab Bandh on 15th July 2010. Indian Medical Association Punjab [Internet]. [cited 2010 Sep 27]. Available from: <http://imapunjab.org/memorandum-for-15th-july.pdf>
5. Indian Medical Association, Bengal State Branch. Observation on the West Bengal Medical Clinical Establishments (Registration and Regulation) Bill, 2009, Bill No. 15 of 2009. Published in the Kolkata Gazette, Wednesday, October 28, 2009 [Internet]. 2009 Oct 28 [cited 2010 Sep 23]. Available from: [http://www.imabengal.org/bills\\_acts\\_rules-byelaws\\_judgements](http://www.imabengal.org/bills_acts_rules-byelaws_judgements)
6. Pandey V. New medical policy to ensure docs don't over-drug patients. *DNA* [Internet]. 2010 Sep 9 [cited 2010 Sep 23]. Available from: [http://www.dnaindia.com/india/report\\_new-medical-policy-to-ensure-docs-don-t-over-drug-patients\\_1435532](http://www.dnaindia.com/india/report_new-medical-policy-to-ensure-docs-don-t-over-drug-patients_1435532)
7. <http://clinicalestablishments.nic.in/En/1070-draftminimum-standards.aspx>
8. Available at the official website of Ministry of Health and Family Welfare <http://clinicalestablishments.nic.in/En/1070-draft-minimum-standards.aspx>
9. Phadke A. The Indian Medical Association and the Clinical Establishment Act, 2010: irrational opposition to

- regulation. Indian Journal of Medical Ethics Vol. VII No 4 October-December 2010;229-233. (SALIENT FEATURES)
10. Pandey V. New medical policy to ensure docs doesn't over-drug patients. DNA. 2010 Sep 9, cited 2010 September 23: <http://www.dnaindia.com>.(THERE ARE MANY PRBLMS)
  11. Sushama A. Quality of Medical Education. Cited 2011 May 3. Available from [http://groups.yahoo.com/group/Quality\\_of\\_Medical\\_Education/message/3265](http://groups.yahoo.com/group/Quality_of_Medical_Education/message/3265).
  12. Ministry of health and family welfare( Department of health and family welfare) Notification, New Delhi, 23<sup>rd</sup> May,2012 (district registry)