### THE CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION ) ACT 2010

KEY POINTS AND FREQUENTLY ASKED QUESTIONS

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#### OPERATIONAL GUIDELINES FOR CLINICAL ESTABLISHMENTS ACT

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

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, except the establishments run by Armed Forces.  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.

#### DATE OF ADOPTION/COMING IN TO FORCE AND NOTIFICATION .

- IN RAJASTHAN
- DATE OF ADOPTION/COMING IN TO FORCE AND NOTIFICATION : 29/08/2011
- DATE OF NOTIFICATION OF STATE RULES : 05/06/2013
- DATE OF NOTIFICATION OF STATE COUNCILS : 05/06/2013
- DATE OF NOTIFICATION OF DISTRICT REGISTERING AUTHORITY (DRA): 05/06/2013

 COVERAGE - All clinical establishments including diagnostic centers and single doctor clinics, across all recognized systems of medicine in both public and private sector. (Exception: establishments of the Armed Forces)

# RECOGNISED SYSTEMS OF MEDICINE

- ALLOPATHIC: Medical and Dental,
- AYUSH: Ayurvedic, Unani, Siddha, Homoeopathy, Yoga, Naturopathy and Sowa Rigpa

- **STANDARD APPLICATION FORM : Application**
- for registration may be made by post, in
- person or online through website.

## REGISTRATION IS MANDATORY UNDER THE ACT

 No one can run a clinical establishment without registration: Within one year from commencement of Act, every existing Clinical **Establishment has to apply for registration** within one year from commencement of Act and every new Clinical Establishment i.e. which has come into existence after commencement of Act has to apply for registration within six months from the date of its establishment.

### TWO TYPES OF REGISTRATION:

 1.Provisional Registration: No enquiry is to be done prior to grant of certificate of provisional registration, which is granted for one year at a time.

 <u>The authority shall not undertake any enquiry</u> prior to grant of provisional certificate and grant the provisional certificate within ten days from the receipt of such application.

- 2. PERMANENT REGISTRATION :
- Permanent registration is to be considered after notification of Minimum Standards.

 Clinical Establishments will be required to meet" <u>Minimum Standards</u>" before grant of Permanent Registration • TIME LIMIT :

 The provisional registration shall not be renewed after a period of two years from the date of notification of minimum standards, in case of existing clinical establishments and same shall not be renewed after a period of six months in case of new clinical establishments. ( i.e. which come in to existence after the date of notification of minimum standards)

#### **CERTIFICATE OF PERMANENT REGISTRATION**

#### **IS GRANTED FOR FIVE YEAR AT A TIME**

### APPLICATION FOR MORE THAN ONE CATEGORY OF SERVICES:

If the clinical establishment is offering services more than one category as classified by the central government under subsection 1 of section 10 of the act ,it shall apply for a separate provisional/permanent registration for each category of services offered by the clinical establishments. However, if laboratory or diagnostic centre is a part of clinical establishments providing outpatient /inpatient care,

**NO SEPARATE REGISTRATION SHALL BE REQUIRED.** 

#### **FEES TO BE CHARGED:**

• In Rajasthan, following amount of fees is charged for registration, according to

#### RAJASTHAN GOVERNMENT CLINICAL ESTABLISHMENTS(REGISTRATION &REGULATION )RULES, 2013.

Fees to be Charged						
Description	Urban	Urban	Rural	Rural	Metro	Metro
	Provision	Permanel	Provisiona	Permanent	Provisional	Perman
	-al	-nt				-ent
Out Patient	L	200		100	100	500
Care			-			
In Patient Care:						
1 to 30beds		200	14	100	100	500
30 to 100 beds	100	500	50	250	200	1000
Above 100 beds	200	1000	100	300	300	1500
Testing &						
Diagnostic:	100	500	50	250	200	1000
Laboratories	Contraction of the second	1000	100	300	300	1500
Diagnostic & Imaging Centre	200			- Contraction		

#### **Other Fees:**

- (i) For Renewal half the amount of registration fee (Provisional / Permanent)
- (ii) For Late Application, along with the renewal fee, Rs. 50/per day late fee upto the date of filling application for renewal of the registration (Provisional / Permanent) shall be charged.
- (iii) For Duplicate Certificate, the amount shall be Rs. 100/-.
- (iv) For change of ownership, management or name of establishment shall be Rs. 100/-.
- (v) For any appeal the amount shall be Rs. 1000/-.
- Note: If a laboratory or diagnostic center is a part of a establishment providing outpatient / Inpatient care no separate registration is required.



#### 1.What does 'clinical establishment' mean?

A clinical establishment means a hospital, maternity home, nursing home, dispensary, clinic, sanatorium, or any other institution that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine. It also includes laboratory and diagnostic centre or any other place where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other services with aid of laboratory or other medical equipment are carried out. (Please refer to the Definition in the CEA 2010.)

#### **2**. Who is covered under this Act?

All clinical establishments across all recognized systems of medicine (i.e. Allopathy, Ayurveda, Yoga, Naturopathy, Homoeopathy, Siddha, Unani and Sowa Rigpa) in both public and private sector are covered under this Act. This includes, all establishments owned, controlled or managed by the Government, a trust (public or private), a corporation registered under a Central, Provincial or State Act (whether or not owned by the Government), a local authority and a single doctor.

3. Does this law apply to the entire country?

No. This Act has come into force in the States of Arunachal Pradesh, Sikkim, Mizoram, Himachal **Pradesh and all Union Territories (namely Andaman &** Nicobar Islands, Chandigarh, Dadra & Nagar Haveli, **Daman & Diu, Lakshadweep and Punducherry ) except** Delhi from 01 March 2012. The States of Uttar Pradesh, Bihar, Rajasthan, Jharkhand and Uttarakhand have adopted the Act by passing resolution in their respective State assemblies. All clinical establishments in above mentioned States and Union Territories will need to register under this Act. Other states may adopt the law by passing a resolution in their state assemblies under clause (I) of Article 252 of the Constitution.

### 4.Will the same standards apply to all clinical establishments?

NO,Clinical establishments will be classified into different categories. And Different standards are prescribed for different categories.

#### 5. What is the Objective of the Act?

The purpose of Clinical Establishment Act is to make available a database of Clinical Establishments which are authorized to function. Therefore the overall objective is improvement in public health quality by eliminating quacks. Other objectives are: To prescribe basic minimum standards for different categories of clinical establishments for ensuring provision of proper healthcare by the clinical establishments. To collect the required statistics from clinical establishments for policy formulations, planning, implementation, response and evaluation.

6. Who is responsible for registering a clinical establishment under this Act?

The owner of the clinical establishment is responsible for registering the clinical establishments under this Act.

#### 7.Who is the registering authority?

A multi member authority at district level known as the District Registering Authority is the registering authority for clinical establishments located in that district.

- 8..What is the composition of the District Registering Authority?
- The district registering authority will comprise of District Collector as chairperson, District Health Officer / Chief Medical Officer as convener and 6 three other members nominated by the District Collector/District Magistrate.
- The three nominated members shall include
- , a) A senior level officer of the local self-Government at the district level
- , b) One representative from a professional medical association or body having presence, preferably within the district or within the State like IMA or AYUSH.
- c) City Police Commissioner or Senior Superintendent of Police (or his nominee), whose help is required if the particular Clinical Establishment does not cooperate with the district registering authority and refuses to give permission to the teams visiting his or her clinical establishment's premises.

## 9.Am I required to display my certificate of registration?

Yes, the certificate will be displayed at a prominent place from where it is clearly visible.

10.If I buy/hire a clinical establishment which is registered, do I need to apply again for registration?

In the event of Change of ownership/management, the Clinical establishment shall inform the authority of such change in writing duly signed by both old and new owner. **11.If there is change in person in charge,** what is the procedure?

If no change in category just intimate DRA and correct at the time of renewal .

#### **12.What is the procedure for registration?**

The registration can be done in following ways: In person by visiting office of District CMO• By post by sending filled in application along with proof of payment• of fee Online by visiting website www.clinicalestablishments.nic.in 13.Where can I register my clinical establishment? Or what is the process of registration?

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

### **14.What are the documents required for registration?**

For purpose of provisional registration, an application form in the prescribed proforma along with the prescribed fee or proof of payment of prescribed fee as determined by the State Government will be required. **15.What is provisional registration?** 

There are two types of registration provisional and permanent. Provisional registration would be provided on 'as is where is basis.' Provisional Registration would be granted within 10 days of application being filed **16.Will there be inspection before I am granted a provisional registration certificate?** 

For purpose of provisional registration there shall not be any inquiry or inspection prior to grant of registration. However the owner of clinical establishment is expected to fill in all data correctly & shall be responsible for it. The person in charge shall be a medical person holding a qualification of a recognized system of medicine.

## 17.Once I receive a provisional certificate of registration, what is the validity?

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 on annual basis for maximum of two years.

### **18.Is there a penalty for not registering a clinical establishment under this Act?**

No one can run a clinical establishment without registration. Yes, monetary penalty would be imposed. In case, a clinical establishment is being run without registration:

First contravention - up to Ten thousand rupees Second contravention – up to Fifty Thousand rupees• Any subsequent contravention -may extend to five lakh rupees.• If a Clinical establishment fails to pay fines imposed it would be recovered as an arrear of land revenue. The clinical establishment may be shut down by district administration. All orders of Registering Authority would be appealable. 19. There are many Clinical Establishments run by practitioners who do not hold recognized qualification. If they are not registered? Why should I register?

Clinical establishment in states that adopt the Act cannot run without registration; if any clinical establishment is found to run without registration there is monetary penalty. The clinical establishment may be shut down by district administration.

#### 20.How do I register as a user?

There are two procedures to start registration, First click on, "To Register Clinical Establishments (Provisional)" and then click on create new account button, fill information required by user (e.g. Applicants Name, Establishment Name, Email, Log in, Id Proof, Verification Code).

a. A new account will be created. For Creation of New Account Link: http://clinicalestablishments.nic.in/Authenticated Pages/Users/Signup\_ And proceed as instructed. Web based training module is available on the home page of website, which may be accessed for better understanding. **21. From where can I access this site?** 

This can be accessed from the website. URL is

• <u>www.clinicalestablishments.nic.in</u>

#### 22. Can someone else register on my behalf?

Yes

23.How do I know that my application has been submitted successfully and received?

If online provisional registration form is submitted successfully then you can log in again with your password and check your status. It will either show approved/pending/rejected.

# THANK YOU

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