

Frequently Asked Questions

I. QUESTIONS RELATED TO THE CLINICAL ESTABLISHMENTS ACT

1. What is the Clinical Establishments (Registration & Regulation) Act, 2010?

The Clinical Establishments Act provides for registration and regulation of clinical establishments in the country with a view to prescribe basic minimum standards of facilities and services of particular type being provided by the clinical establishment.

2. 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.)

3. 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.

4. Are there any specific clinical establishments that would be outside purview of the Act?

The clinical establishments owned, controlled or managed by the Armed Forces are not covered under this Act.

Also those categories of Clinical Establishment exempted by the state Government and Clinical Establishments located in the States/UTs mentioned in the schedule to the Act; unless these States/UTs repeal their existing Act and adopt Clinical Establishments Act.

5. 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 Puducherry) 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.

6. What are the salient features of the Act?

(i) The Act:

- (a) Assists in generation of reliable and comprehensive database (or registry) for all types of clinical establishments in the country at district, state and national level.
- (b) Helps classify various types of clinical establishments into categories & determine category wise basic minimum standards.
- (c) Defines basic minimum standards for operation, using participatory and consultative approach to ensure uniformity across all establishments. The minimum standards indicate basic standards which are mandatory and certain standards which are desirable.
- (d) Assists Government in obtaining information and data required from clinical establishments for public health interventions including outbreak and disaster management

- (ii) It establishes the multi-stakeholder bodies namely National Council for Clinical Establishments at National level, State Council for clinical establishments at State level & District Registration Authority at each district. Implementation of the Act is by respective state through State council and District Registration Authority.
- (iii) The Act allows for two-step process of registration – provisional and permanent registration. Provisional registration is done through a process of self-declaration, without any inquiry or inspection. Permanent registration would be undertaken after categorization, classification and notification of category wise minimum standards.
- (iv) The Act places the entire process of registration and the data of clinical establishments in the public domain which ensures transparency.
- (v) Details of charges, facilities available would be prominently displayed at a conspicuous place at each establishment
- (vi) Registry of clinical establishments would aid in policy formulation and resource allocation.
- (vii) Cancellation of registration would occur at any time, if conditions for registration are not complied with.
- (viii) Clinical Establishment to provide emergency medical treatment within staff and facilities available.
- (ix) The Act may control or act as deterrent against quackery by introducing registration which is applicable only to clinical establishments of recognized systems of medicine and no one can run a clinical establishment without registration.
- (x) It lays down provisions for healthcare providers to maintain records and reporting as prescribed and provide information and statistics that may be asked for by the authority.

7. Health is a State subject. What is the role of the Central Government and State Governments in implementation of the Act?

It is true Health is a state subject and in the same so the Act is not enforced on any state. State has to adopt the Act by passing a resolution in the legislature assembly of state. The Bill was passed by Parliament after 4 states agreed to enforce the Act after notification.

As per the provisions of the Act,

The Central Government is responsible for:

- Notification of the Act (Completed)
- Notification of the National Council and Rules for the functioning (Completed)
- Classification & Categorization of the Clinical Establishments by Central Government based on the recommendations of the National Council. (Completed)
- Establish Minimum Standards for the different categories of Clinical Establishments based on the recommendations of the National Council.
- Develop and prescribe the form and manner in which the registry (National, State & District level) is to be maintained.
- Provide oversight and assistance to the States and UT's for the implementation of the CEA 2010 including capacity building.
- Assistance for the drafting of Rules under Section 54 of the Act. Draft of Model Rules circulated to all implementing States/UTs.
- Assist States & UT's in adoption of the proposed web based registration system and offline registration systems.
- Assistance to the State & UT's Councils for any other matter that may be required.

The State Governments would be responsible for:

- Notification of State Rules under Section 54 of the Act
- Constitute & notify the State / Union Territory Council of Clinical Establishments
- Constitute & notify District Registration Authorities in all districts
- Begin the process of provisional registration
- Identification and notification of Registrars of Clinical Establishment at State Level (Director of Health Services) and District level (District Health Officer)
- Disseminate information about the Act and Rules at various levels and among stakeholders

8. 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.

II. QUESTIONS RELATED TO THE ORGANISATION

9. 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.

10. 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.

11. 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

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.

12. How will the district registration authority be established? What is the tenure of the district registering authority?

The State Government shall establish the district registering authority by way of notification. The three nominated members shall have tenure of two years.

13. What are the functions of the district registering authority?

In case of provisional registration, the District Health Officer or Chief Medical Officer shall:

- Accept for purpose of provisional registration, application in the prescribed proforma as adopted by the State Government along with the requisite fee as determined by the State Government.
- Accept applications for provisional registration - either filed in person, or by post or online
- After receipt of application, grant within a period of ten days from date of receipt, a certificate of provisional registration in such form and particulars as determined by the State Government
- Within a period of forty five days from grant of provisional registration, publish all particulars of the clinical establishment, in a manner as may be determined by the State Government.

- Renewal of Registration and issue of duplicate certificate as per the provisions of Act and Rules.

14. What is the composition of the National Council for Clinical Establishments?

The detail composition of National Council for Clinical Establishments may be seen in the Act. National Council is a 20 member body under ex – officio chairman DGHS, MOHFW, Government of India. Officer of rank of Joint Secretary of Ministry of Health and Family Welfare dealing with the subject of Clinical Establishments Act shall be ex-officio secretary of National Council. The National Council has elected members from regulatory councils for allopathic Doctors (MCI, DCI), Pharmacy, Nursing, Indian systems of Medicine (Ayurveda, Soddha, Unani), Homoeopathy, Indian Medical Association (IMA) and nominated representatives of Bureau of Indian Standards (BIS), Zonal council, North Eastern Council other paramedical systems, consumer groups and association of Indian System of Medicine.

15. What are the functions of the National Council for Clinical Establishments?

The National Council shall:

- Compile and publish a National Register of clinical establishments within two years from the date of the commencement of this Act;
- Classify the clinical establishments into different categories;
- Develop the minimum standards and their periodic review;
- Determine within a period of two years from its establishment, the first set of standards for ensuring proper healthcare by the clinical establishments;
- Collect the statistics in respect of clinical establishments;
- Perform any other function determined by the Central Government from time to time.

16. Will the same standards apply to all clinical establishments?

No. Clinical establishments will be classified into different categories.

Different standards are prescribed for different categories.

17. What is the composition of the State Council of Clinical Establishments?

The composition of The State Council is as under:

- Secretary, Health ex officio, who shall be the Chairman;
- Director of Health Services — ex officio member-secretary;
- Directors of different streams of Indian Systems of Medicine -ex officio members;
- One representative each to be elected by the executive committee of
 - State Medical Council of India
 - State Dental Council of India
 - State Nursing Council of India
 - State Pharmacy Council of India
- Three representatives to be elected by the Executive of the State Council or Union Territory Council, as the case may be, of Indian Medicine representing the Ayurveda, Siddha and Unani systems of medicines;
- One representative to be elected by the State Council of the Indian Medical Association;
- One representative from the line of paramedical systems
- Two representatives from the State level consumer groups or reputed non-governmental organizations working in the field of health.

18. What is the function of the State Council / Union Territory Council of Clinical Establishments?

Every State adopting this Act would set up multi-member State Council for Clinical Establishments to perform the following functions:

- Compiling and updating the State Registers of clinical establishment;
- Sending monthly returns for updating the National Register;
- Representing the State in the National Council;
- Hearing of appeals against the orders of the authority;
- Publication on annual basis a report on the state of implementation of standards within their respective States.

III. QUESTIONS RELATED TO THE ACTIVITIES UNDER THE ACT

19. In case of grievances, who can be contacted?

- 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 can prefer an appeal to the State Council.

20. Can an individual seek redressal of his grievances?

Yes. However, the Act provides only for action against clinical establishment that is in default of the Law.

21. What are the institutional mechanisms set up under this Act?

- National Council for Clinical Establishments at central level
- State Council for Clinical Establishments at state headquarters level.
- District Registering Authority at District Headquarter level.

22. What are the conditions for registration of a clinical establishment under this Act?

For registration and renewal the conditions to be fulfilled by Clinical Establishments are:

- (i) The Minimum standards of facilities and services as may be prescribed;
- (ii) The minimum requirements of personnel as may be prescribed;
- (iii) Provisions for maintenance of records and reporting as may be prescribed;

- (iv) The clinical establishment shall undertake to provide within the staff and facilities available such medical examination and treatment as may be required to stabilize the emergency medical condition of any individual who comes or is brought to such clinical establishment.

Other conditions are:

- (i) Display the Registration certificate at a prominent place.
- (ii) Display the rates charged for each type of service provided and facilities available, for the benefit of patient at a conspicuous place in local language and in English.
- (iii) Charge the rates for each type of procedures and services within the range of rates determined and issued by the Central Government from time to time, in consultation with the State Governments.
- (iv) Ensure compliance with Standard Treatment Guidelines as may be determined and issued by the Central Government or State Government, as the case may be, from time to time.
- (v) Maintain and provide Electronic Medical/Health Records of every patient, as may be determined and issued by the Central Government or State Government, as the case may be, from time to time.
- (vi) Maintain and provide information and statistics in accordance with all other applicable laws that are in force and rules made thereunder.

IV. QUESTIONS RELATED TO THE INDIVIDUAL CLINICAL ESTABLISHMENTS

23.If the Act is not applicable to my state, do I still need to register under the Act?

No

24. 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.

25.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.

26.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.

27.If my clinic is shifted to another location in same district, then what is the procedure to be followed?

In event of change of major or broad location or on ceasing to function as a clinical Establishment, the certificate in respect of such clinical establishment shall be surrendered to the authority and Clinical Establishment shall apply for registration again.

28.If I upgrade my already registered clinic into a nursing home or add a laboratory with it, what is the procedure to be followed?

In case of change of major or broad category (e.g. clinic, hospital, Laboratory, Imaging centre, change in system of medicine) the certificate in respect of such clinical establishment shall be surrendered to the authority and Clinical Establishment shall apply afresh for registration.

29.If I move my facility to some other district, what is the procedure to be followed?

In event of change of location the certificate in respect of such clinical establishment shall be surrendered to the authority and Clinical Establishment shall apply afresh for registration.

30. Am, I need to seek accreditation, if I am registered under the act?

Accreditation is voluntary and there is no compulsion on Clinical Establishment for same.

31. Do, I require to provide emergency treatment to all patients who come to my establishment in emergency?

Under the Act, the Clinical Establishment is required to stabilize emergency medical conditions with in staff and facilities available.

32. Who is going to pay for treatment given to patients in emergency?

It is the responsibility of the clinical establishment to provide treatment in emergency medical condition within staff and facilities available. (This is clearly mentioned in the Medical Code of ethics 2002 also.) The Act does not prohibit the clinical establishment from charging the patient/ his family members. However treatment within staff and facilities available cannot be denied on any ground.

33. I am accredited by NABH. Do I still need registration?

Registration will be compulsory under the ACT in the states/UTs wherever the Act is or would be applicable even if accredited by NABH.

V. QUESTIONS RELATED TO THE REGISTRATION

34. 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

35. 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).

36. 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.

37. 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.

38. What is Permanent registration?

Once minimum standards have been notified by the Govt. for the Clinical Establishments, Permanent registration would be provided to all those conforming to the notified standards prescribed for that category of clinical establishments.

39. Does my application necessarily have to be in English?

It can be both in English & Hindi.

40. Who will issue the registration certificate?

The District Registering Authority shall issue the registration certificate, the office of which is located in the office of District CMO.

41. 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.

42. 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.

43. When do I need to renew my 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.

44. When will permanent registration be undertaken?

Permanent registration will commence after minimum standards are notified. Clinical establishments are given sufficient time as per guidelines of Act to prepare themselves to meet minimum standards.

**45. Will provisional registration continue after permanent registration begins?
/ Is permanent registration mandatory after notification of standards or
can I continue to run Clinical Establishment with provisional registration?**

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 before the commencement of this Act
- 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 two years from the date of notification of the standards, which came into existence after standards have been notified.

46. 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.

47. What is the procedure for Appeals?

Procedure for appeal is laid down in state rules and guidelines provided on procedure for appeals are as under

- In keeping with Section 36, 41 (4) (5) (6) (7) and Section 42 (4) (5) (6) (7), any person or clinical establishment, if aggrieved by the decision of the Authority under Sections 29 and 34 of the Act, may file an appeal within thirty (30) days from the date of receipt of such order along with a fee as prescribed by the State Government.
- The appeal against a public healthcare establishment shall be filed in prescribed format and shall be sent to the state council by registered post or in person.
- Every appeal shall be accompanied by a fee.

- After receipt of the appeal, the State Council shall fix the time and date for hearing and inform the same to the appellant and others concerned by a registered letter giving at least 15 days time for hearing of the case.
- The appellant may represent by himself or authorized person or a Legal practitioner and submit the relevant documentary material if any in support of the appeal
- The State Council shall hear all the concerned, receive the relevant oral/documentary evidence submitted by them, consider the appeal and communicate its decision preferably within 90 days from the date of filing the Appeal
- If the State Council considers that an interim order is necessary in the matter, it may pass such order, pending final disposal of the appeal.
- The state council will have the authority to stay the operation of the order of the district authority till such time as it deems necessary.
- The decisions of State Council shall be final and binding.
- If no appeal is filed against the decision of the Registering Authority in the prescribed period (i.e.) within 30 days from the date of receipt of the order, the orders of the Authority shall be final.
- The appeal fees collected by the authorities shall be deposited by the Authority concerned in a Nationalized bank account opened in the name of the official designation of the State Council concerned and shall be utilized by the Council and authority for the activities connected with the implementation of the provisions of the Act as approved by the Council.

48. Does for any Clinical Establishment registered under this Act ensure high quality of treatment/service by that clinical establishment?

Yes

49. What is the benefit for the clinical establishment by registration under the Act?

- Provisional Registration is without any inquiry or inspection, on the basis of the information submitted by the establishment
- Registration will also help isolate and identify the hundreds of thousands of quacks that are playing havoc with the lives of millions of people all over the country.
- Once in place, the system of registration will help in improving the standards of healthcare establishments within a couple of years. It will also bring about some uniformity in the standards of care across the country.
- Registration will help the Clinical Establishment become part of district, state and National registry and help government to collect necessary inventory for better healthcare management and allocation of infra structure, human resources, equipment's ,logistics etc.
- There will be enhanced trust of patients in the Clinical Establishments registered under the Act, which indirectly will augment their market value.

50. What is the benefit for patients?

- Patients will be provided improved quality of health care and patient safety will be ensured through compliance to Minimum standards, Standard Treatment Guidelines and preventing unqualified persons from running Clinical Establishments..
- Better management of Emergency medical conditions
- Details of charges, facilities available would be prominently displayed at a conspicuous place at each establishment so clinical establishments will not charge exorbitantly as is happening in many cases currently.
- Patients are assured of proper healthcare by Clinical Establishment registered under the Act.

51. 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.

VI. QUESTIONS RELATED TO THE PROCESS OF REGISTRATION UNDER CLINICAL ESTABLISHMENT ACT

52. 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/AuthenticatedPages/Users/Signup_New.aspx

And proceed as instructed.

Web based training module is available on the home page of website, which may be accessed for better understanding.

53. From where can I access this site?

This can be accessed from the website. URL is www.clinicalestablishments.nic.in

54. What happens if I forget my password?

In this case click on "To Register Clinical Establishments (Provisional)" and use "forgot password?" link. Fill information regarding retrieval password (e.g. Login id and Email Id). And Click on Continue button.

OR

You click on forgot password link:

<http://clinicalestablishments.nic.in/AuthenticatedPages/UserManagementContent/ForgetPassword.aspx>

55. What if I do not receive a registration confirmation email?

This will happen if, you fill wrong email id.

56. What if I do not receive a registration confirmation email?

Please contact District Registration Authority, i.e. office of District CMO of your district.

57. Can someone else register on my behalf?

Yes

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

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

59. Will I get an acknowledgement once I apply for registration?

You will have to log in with user id and password and download your provisional Certificate.

60. In case of online application, whom do I contact if I have questions about my application?

If any doubts on online provisional registration application please contact your District Registration Authority i.e. office of District CMO of your District alternatively office of DM can be contacted.

61. Can I save my application and submit at later date?

Yes, save as draft in online application; “save as draft” option is available before the submission.

62. How do I enquire about the status of my application?

Please login with the owner login id and password and check status of online application.

63. What is the next step once I submit the application?

Once online application form is submitted, its status shows pending till District Registration Authority approves and once it is approved, download pdf format of Provisional registration Certificate.

64. Will my information be visible to anyone?

No it will only be visible to you and District Registration Authority.