Draft

OPERATIONAL GUIDELINES FOR CLINICAL ESTABLISHMENTS ACT

INTRODUCTION

The Clinical Establishments (Registration and Regulation) Act, 2010

(A tool to improve healthcare)

The Clinical Establishments Act was passed by Parliament on 17th August 2010, to provide for registration and regulation of all clinical establishments in the country with a view to prescribing the 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 have adopted the Act under clause (1) of article 252 of the Constitution. So as on date the Act is applicable in aforesaid 10 states and 6 Union Territories.

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.

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 Establishment Act.
- Also Clinical Establishments of those categories and of those recognised system of medicine for which date has not been appointed by the state Government, who has other wise 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.

Objectives of the Act

The specific objectives are

i) To establish digital registry of Clinical Establishments at National, State and District level.

ii) To prevent **quackery** by unqualified practitioners by introducing registration system, which is mandatory.

iii) To prescribe **minimum standards of facilities and services** for all categories of health care establishments (except teaching hospitals, health care) and ensure compliance of other conditions for registration like standards treatment protocols, display of range of rates to be charged, maintenance of records.

Need of Legislation

- Article 47 (Constitution) mandates improvement in public health, thus the Government is required to take all measures for this purpose.
- As per NSSO data of 60th round, the private sector today provides nearly 80% of outpatient care and about 60% of inpatient care. By NSSO estimates as much as 40% of the private care is likely to be by informal unqualified providers. In terms of comparative efficiency, public sector is value for money as it accounts (based on the NSSO 60th round) for less than 30 % of total expenditure, but provides for about 20% of outpatient care and 40% of in-patient care. This same expenditure also pays for 60% of end of-life care (RGI estimates on hospital mortality), and almost 100% of preventive and promotive care and a substantial part of medical and nursing education as well.
- In India, out-of-pocket payments still account for a very large share, 59–71% of total health spending. Most such payments are made to private providers.
- There is unprecedented growth of Private sector but it largely remains unregulated. Thus health regulation continues to be unresolved.
- Majority of states have either no legislations or outdated /ineffective legislation many of which have also not been implemented by the States.
- Thus there is a general perception that current regulatory processes are inadequate or do not ensure health care services of acceptable quality and that which prevent negligence. There are always concerns on how to improve health care quality.
- There is lack of complete information with the policy makers regarding available health care resources in different parts of the country which is required for appropriate policy formulation.
- No systematic collection of information from private health establishments.

Global Scenario of Health Regulation

Accreditation of hospitals began way back in 1910 in the United States of America, when "end result system of hospital standardization" was proposed. This was the stated objective of American College of Surgeons that developed the first Minimum standards for hospitals in the year 1917 whilst in United Kingdom Health Quality Services is accredited by ISQua and HQS is the oldest health accreditation service in Europe.

The trending Health reforms and scenario amongst BRICS nations which are diverse in so many ways but united by their common experience of high economic growth and aspiration to improve the health of their citizens. Notably, all BRICS countries have increased government spending on health and have provided subsidies for the poor. However, such improvements will not guarantee universal coverage in the absence of efficiency and accountability. The administrative systems in Brazil, India and the Russian Federation – entail a division of power and responsibility between the central government and states. Although they are made at the central level, national policies often have to be implemented by sub national entities that are largely autonomous. This often leads to multiple sources of fragmentation and potential for the duplication of efforts and consequent inefficiencies. The constitution of Brazil delineates the basic structure of the Unified Health System the Sistema Único de Saúde in terms of the decentralization of the responsibility for the management of health services to the sub national levels of government.

In India where, constitutionally, health is a state responsibility – central schemes such as the National Health Mission offer funding to states to induce them to follow the national reform's vision.

In China, the central government sets broad policy guidelines but leaves the implementation details to local governments. In China and India, the centre still has little administrative control over implementation and the quality of any implementation can vary considerably across sub national entities. The health sector in these countries is characterized by mixed health systems in which both the public and private sectors provide health services. Where the private sector for health-care delivery is large, universal health coverage is most likely to be achieved through the strategic purchasing of services from both the public and private providers of health care. Some BRICS countries have attempted this type of purchasing. For example, government-sponsored health insurance in India enables the purchase of hospital services from both public and private hospitals. South Africa's National Health Insurance Fund also enables the government to draw on human resources located in both the public and private health sectors.

In South Asian countries like Malaysia, The Malaysian Society for Quality in Health (MSQH) was formed by combined efforts of the Ministry of Health Malaysia and Association of Private Hospitals of Malaysia. It is strongly supported by the Ministry. Thailand introduced universal coverage reforms in 2001, becoming one

of only a handful of lower-middle income countries to do so. The majority of health care services in Thailand are delivered by the public sector.

Regulatory frameworks in the health sector assume a variety of forms in different countries. One of the first challenges the countries have faced in planning for regulation and accreditation systems is to gain consensus on the definitions of various forms of regulation and evaluation, licensure, certification .

Accreditation and Regulation of healthcare organizations with Minimum standard has been used in many countries as tools for defining the required characteristics of acceptable healthcare services. Their voluntary or mandatory nature varies as a function of system objectives. The following definitions are based on technical support experiences in various countries:

1. Licensure: a government administered mandatory process that requires healthcare institutions to meet established minimum standards in order to operate.
2. Certification: a voluntary governmental or non-governmental process that grants recognition to healthcare institutions that meet certain standards and qualifies them to advertise services or to receive payment or funding for services provided.
3. Accreditation: a process by which a government or non-government agency gives recognition to healthcare institutions that meet certain standards that require continuous improvement in structures, procedures or outcomes. It is usually voluntary, time-limited and based on periodic assessments by the accrediting body, and may, like certification, be used to achieve other desirable ends such as payment or funding.

Present Status of Regulation of Health Care Infrastructure and Services in India

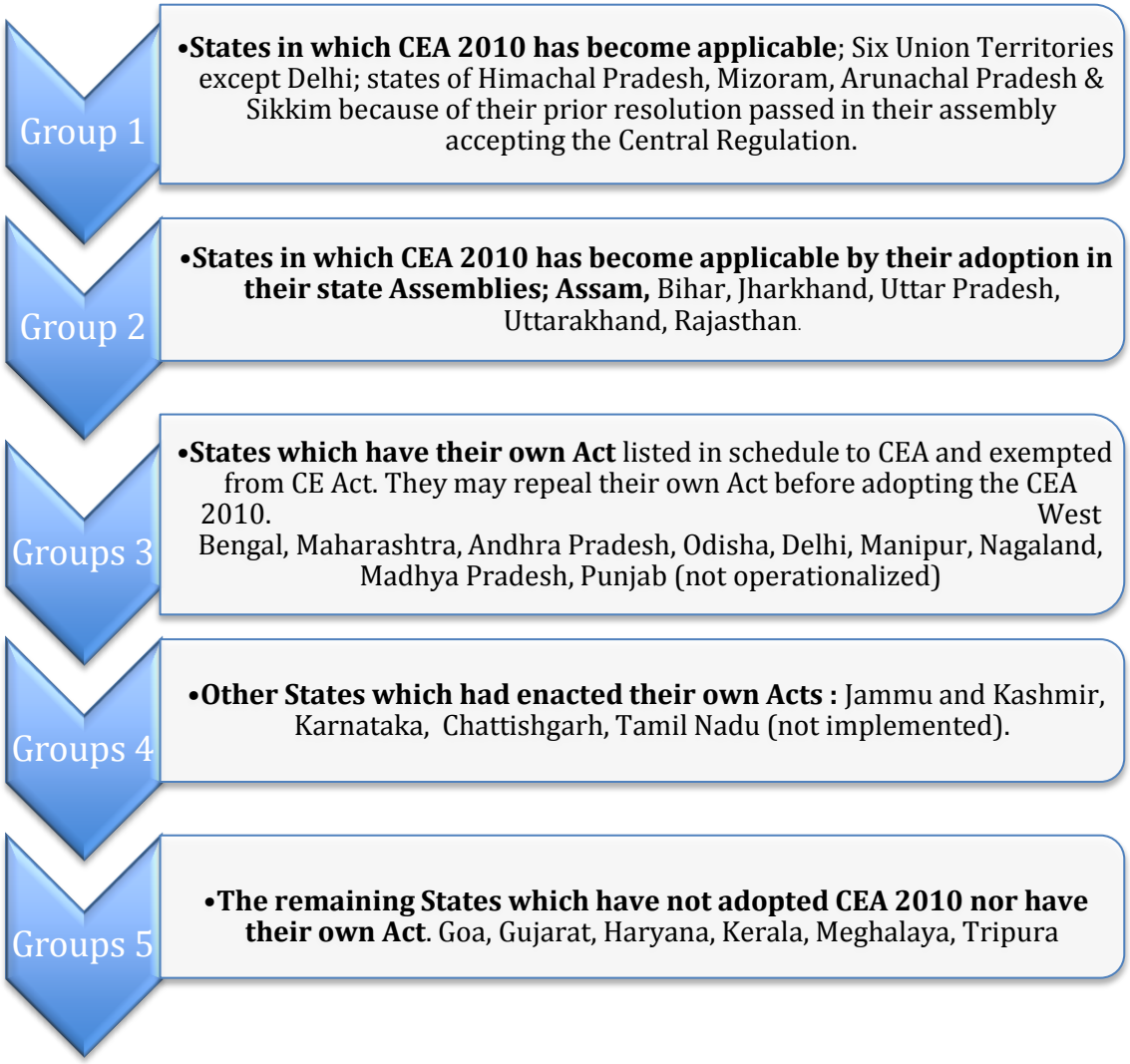
Healthcare in India suffers from under regulation subjecting the populace to poor quality of treatment, quackery menace and high costs. This makes it imperative to enforce minimum standards on Clinical establishments in both private and public sector. The private sector has a vast range of service providers from the highly competent to the quacks. Patient safety is compromised here and financing and service delivery are not transparent and accountable, making delivery of healthcare prejudiced against the poor. High cost of Healthcare in private sector raises the issue of affordability and also equity. Technical quality of Health care depend on factors like competence of personnel involved, adherence to clinical protocols, standard treatment guidelines as well as availability of required facility and infrastructure which are ensured in accredited hospitals but remains suspect in non-accredited institution.

REGULATION OF MEDICAL PROFESSIONALS:

Statutory regulatory councils have been established to monitor the standards of medical education, promote medical training and research activities, and oversee the qualifications, registration, and professional conduct of doctors, dentists, nurses, pharmacists, and practitioners of other systems of Medicine such as Ayurveda, Yoga, Unani, Siddha and Homeopathy.

Important of these laws are: the Indian **Medical Council** Act, 1956, the Indian **Nursing Council** Act, 1947; the **Indian Medicine** Central Council Act, 1970; the **Homeopathy Central** Council Act, 1973; and the **Pharmacy** Act,1948. Almost all of these laws establish councils that set forth **uniform** educational and **qualification standards. Regulation of Medical professionals already exists under Medical Council of India, Code of Medical Ethics, 2002 may be seen on Website .**

The Summary of Health Regulations in States/UTs as on 21-03-2016



Parameter	States/UT's
States repealing existing legislations and enacting own acts on lines of CEA, 2010 ***(3)***	**Maharashtra, Goa & Delhi (?)** are in the process of repealing existing legislation & enacting one on the lines of CEA with modifications.
States enacting legislations where there was no legislations ***(4)***	**Kerala, Gujarat, Haryana & Meghalaya** are in the process of enacting legislation on the lines of central act with modifications
Other States which have own Act ***(4)***	**J&K, Andhra Pradesh (erstwhile), Chhattisgarh, Karnataka, Tamil Nadu (not implemented), (Not implemented)**
States which have their own legislations, listed in schedule to CEA and exempted from CE Act. ***(9)***	Andhra Pradesh Maharashtra Delhi Madhya Pradesh Manipur Nagaland Punjab Orissa West Bengal

States/UTs where Clinical Establishments Act (CEA) is applicable (16)

Parameter	States/UT's
Notification of State rules	Notified by – **Arunachal Pradesh, Himachal Pradesh, Bihar, Jharkhand, Sikkim, Uttarakhand, Rajasthan, Andaman & Nicobar Islands, Daman & Diu, Dadra & Nagar Haveli, Puducherry, Mizoram, Chandigarh** Not notified – **U.P. , Assam** **Lakshadweep (No private Clinical Establishments)** **Uttarakhand: rethinking on changing rules**
Notification of State / UT council	Notified by – **Arunachal Pradesh, Himachal Pradesh, Sikkim, Bihar, Uttarakhand, Jharkhand, Rajasthan, Andaman & Nicobar Islands, Lakshadweep, Daman, Diu, Dadra & Nagar Haveli, Puducherry, Mizoram** Not notified: **-- U.P., Assam, Chandigarh**
Notification of District Registration Authorities	Notified by - Arunachal **Pradesh, Himachal Pradesh, Bihar, Uttarakhand, Jharkhand, Sikkim, Andaman & Nicobar Islands, Daman, Diu, Dadra Nagar Haveli, Puducherry (2/4). Rajasthan, Chandigarh, Mizoram** Not notified: **-- U.P., Assam**

Salient Features of Clinical Establishments Act 2010 and Clinical Establishments (Central Government) Rules 2012

Definition: Clinical Establishment

(i) a hospital, maternity home, nursing home, dispensary, clinic, sanatorium or an institution by whatever name called that offers services, facilities requiring diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognized system of medicine established and administered or maintained by any person or body of persons, whether incorporated or not; or

(ii) a place established as an independent entity or part of an establishment referred to in sub-clause (i), in connection with the diagnosis or treatment of diseases where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services with the aid of laboratory or other medical equipment, are usually carried on, established and administered or maintained by any person or body of persons, whether incorporated or not, and shall include 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

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

- **Date of commencement of the Act**: it is the date on which the Act shall come into force in a State and it is the date on which a state adopts the Act under clause (1) of Article 252 of the constitution by passing resolution to this effect in the state legislatures. Thus the provisions of the Act became applicable from the date of adoption of the Act by the State.

  Provided that different dates may be appointed for different categories of clinical establishments and different recognised system of medicine

- **Recognized systems of medicine**:
  - Allopathic: Medical and Dental,
  - AYUSH:Ayurvedic,Unani,Siddha,Homoeopathy,Yoga,Naturopathy and Sowa Rigpa(Sowa Rigpa was recognized under AYUSH by the

Ministry of AYUSH after passing of Clinical Establishments bill by the Parliament).

- **Registry:** Digital registry of Clinical Establishments at National, State & District level.
- **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 exiting Clinical Establishments has to apply for registration within one year from commencement of Act and every new Clinical Establishment i.e. which come into existence after commencement of Act has to apply for registration within six months from the date of its establishment.
- **Act provides for two types of registration:**
  - **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
  - **Permanent registration:**
    - Permanent registration is to be considered after notification of Minimum Standards. Clinical Establishments will be required to meet Minimum Standards before grant of Permanent Registration.
    - The provisional registration shall not be renewed after a period of two years from the date of notification of Minimum Standards, in case of exiting Clinical Establishments and the same shall not be renewed after a period of six months in case of new Clinical Establishments (i.e. which come into existence after date of notification of Minimum Standards). Certificate of permanent registration is granted for five year at a time.

Conditions to be fulfilled by every Clinical Establishment for Grant of Registration (Permanent) and continuation

1. Minimum standards of facilities and services;
2. Minimum requirement of personnel;
3. Provision and maintenance of records and reports
4. Every clinical establishment is required to provide treatment "**with in the staff and facilities available**" to stabilize the emergency medical condition of an individual who comes or is brought to the clinical establishment.
5. Other conditions (as prescribed under Central Govt. Rules)
   - **Details of rates charged and facilities available** to be prominently displayed at a conspicuous place in local and in English language
   - **Maintain and provide Electronic medical records or Electronic Health records of every patient as** may be determined and issued by Central/State Govt.

- Clinical Establishments shall **charge the rates for procedures and services within the range of rates** determined by the Central Government from time to time in consultation with the State Governments.
- Clinical Establishments shall ensure compliance to **Standard Treatment guidelines** as may be issued by Central/State Govt.
- Every Clinical Establishments shall maintain information and statistics in accordance with all applicable laws and rules.

6. **Fee for registration, renewal and appeal**
   - Shall be specified by respective State Government/UT administration under section 54
   - State/UT may charge fee category wise
   - Enhanced fee may be charged if renewal not applied within the prescribed time
   - State Government/UT Administration may charge fee for appeal made to state/UT Council

7. **Time period to Apply for Renewal of Registration**
   - 30 days before expiry of the validity of certificate in case of provisional registration
   - 6 months before expiry of the validity of certificate in case of permanent registration

8. **Cancellation of registration of clinical establishment after registration is granted**
   1. If condition of registration are not being complied
   2. Person who is responsible for management of the Clinical establishment has been convicted of offence under this Act
   3. If there is imminent danger to the health and safety of patients, then after cancellation, the authority may immediately restrain

9. **Penalties under the Act:**
   No imprisonment under this Act
   Monetary penalties: Rs 10000 to 5 lakh; depends on size, category, type and local conditions

Offence	**Penalty in Rupees upto**		
	First offence	Second offence	Subsequent offence
Running Clinical Establishment without registration	50000	200000	500000
Contravention of any other provision of the Act	10000	50000	500000
Whoever knowingly serves in an unregistered Clinical Establishment	25000		
Minor deficiencies which do not pose imminent danger	10000		

Benefits of Act

- Comprehensive Digital Registry of clinical establishments and systematic collection of information
  - Policy formulation
  - Better surveillance, response and management of outbreak & public health emergencies
  - Engagement with private providers
- Clinical Establishments categorized into categories which makes it feasible to prescribe uniform standards for a category
- Transparency:
  - Process of registration, data in public domain.
  - Details of **charges, facilities available would be prominently displayed** at a conspicuous place at each establishment
- Multi stakeholder participation in institutional mechanisms (National & State Councils, District Registration Authority) – consensus based decisions.
- **Effective Regulation of** providers would occur
- **Improved quality** of health care as care is based on standard treatment protocols and minimum standards
- Increased patient confidence due to Government registration
- Improved brand value of Clinical Establishments
- **Deterrent against quackery:** Under the Act, the registration is mandatory and allowed only for clinical establishments belonging to recognized systems of medicine
- **Better management of Emergency** medical conditions
- **Better records and reports**

The Central Government is responsible for

- Notification of the Act.
- Notification of the National Council and Rules for the implementation of the Act.
- Classification & Categorization of the Clinical Establishments by Central Government based on the recommendations of the National Council**.**
- 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 all technical guidelines including Standard Treatment Guidelines and proformas for collection of statistics
- Collect information and statistics from registered clinical establishments
- Provide oversight and assistance to the States and UTs for the implementation, monitoring and supervision of the CEA 2010 including capacity building.
- Advocacy cum Training workshops in coordination with States
- Assistance in formulation of State Rule under Section 54 of the Act.
- Assist States & UTs in adoption of the proposed web based registration system and offline registration systems.
- Assistance to the State & UTs Councils for any other matter that may be required.

National Council for clinical establishments

Composition of National Council: 20 members including Chairman

- 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 representative**),
- Central Council of Homoeopathy (**one elected representative**) ,
- Indian Medical Association (**one elected representative**),
- Bureau of Indian Standards (**one representative**),
- Zonal Councils set up under the States Reorganization Act, 1956 (**two representative**),

- North Eastern Council (**two representatives**).
- Line of Paramedical systems except systems represented at 2 above (**one**),
- National Level Consumer Group to be nominated by Central Government. (**two**)
- 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, Ex-officio

Functions of National Council:

(a) compile and publish a National Register of clinical establishments within two years from the date of the commencement of this Act;
(b) classify the clinical establishments into different categories;
(c) develop the minimum standards and their periodic review;
(d) determine within a period of two years from its establishment, the first set of standards for ensuring proper healthcare by the clinical establishments;
(e) collect the statistics in respect of clinical establishments;
(f) perform any other function determined by the Central Government from time to time.

Secretary of National Council and Staff of National Council Secretariat

The officer of the rank of Joint Secretary dealing with the subject of Clinical Establishments in the MOHFW, GOI shall be the ex-officio secretary of the National Council for Clinical Establishments

National Council Secretariat

1. DDG level officer – One From existing pool of DDG
2. CMO level officer - One As Nodal officer from existing pool of CMOs
3. Consultant (Clinical Establishment) – One
4. Consultant (IT) – One
5. Section In charge / Section Officer - One
6. Statistical Assistant - One
7. Secretarial Assistants - Two
8. Data entry Operator - One
9. Multitasking Staff - One

Sub-Committees of National Council

The National Council may constitute sub-committees and nominate its Chairman and may appoint to such sub-committee, as it deems fit, persons, who are not members of the National Council, for such periods, not exceeding two years, for the consideration of particular matters.

Subcommittees

Subcommittee	Chairman
Categorization and Classification of CE	Dr. B.Suresh, Vice Chancellor, JSS University, Mysore
Template for Developing Minimum Standards	Dr. B.D. Athani, Special DGHS
Minimum Standards	Dr. Arun K. Agarwal, Addl.DG, Ex-Dean MAMC
Information & Statistics to be collected from CE	Dr. S.Y. Kothari, Ex-Special DGHS
Defining range of rates of Procedures & Services	Dr. B.D. Athani, Special DGHS

Implementation of the Act

Is by respective State Government / Union Territory administration. The institutional arrangements are as under:

At State Level

State Council for Clinical establishments

- Chairman: Secretary Health
- Member Secretary : Director of Health Services;
- Members (14):
  - ✓ Directors of different streams of Indian system of Medicine (3)
  - ✓ Elected Representatives of State Councils: Medical Council, Dental Council, Nursing Council, Pharmacy Council, State council of Indian system of medicine (7)
  - ✓ Elected representative of State council of IMA, (1)
  - ✓ Representative of line of paramedical system (1)
  - ✓ State-level consumer groups or reputed Health NGOs (2)

Functions:

1. Appellate against the decisions of district registering Authority
2. Compiling/updating State Register of Clinical establishments

3. Monthly return for National Register of Clinical establishments
4. Represent State in National Council Meetings
5. Publish Annual report

District Registering Authority

Chairman: District collector/District Magistrate (DM)
Convener: District CMO / CMHO
Three members: to be nominated by DM

(i) City Police Commissioner/SSP/SP or nominee
(ii) Senior officer of local self Govt. at district
(iii)Professional medical Association/body

Powers & Responsibilities: DRA

- **Grant/Renew** provisional (within 10 d)/permanent registration
- **Publish**
  a) **List of PROVISINALLY REGISTERED** (within 45 d after grant),
  b) **Clinical Establishments who submit evidence for permanent registration and invite objections if any(30 d**),
  c) **Expired REGISTRATIONS**
- May **Issue a notice** to Clinical establishment to show cause within 3 months, if condition of registration are not met
- To **enter and search** unregistered CE (after due notice),
- **inspection and inquiry of registered Clinical establishments** through multimember inspection team– Inform the deficiency and actions to be taken by Clinical establishment
- **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
- **Recover penalties**
- Maintain **District register** of Clinical establishments

Additional Staff for implementation of the Act:

State Level: In the office of Directorate of Health Services/State Secretary Health

Name of the Staff	**No. of Staff**	**Suggested Terms of Reference for guidance of States**
State Coordinator	Less than 15 Districts: 1 More than 15 Districts:2	**Annexure 1.**
Administrative Assistant cum Data Entry Operator	Less than 15 Districts: 1 More than 15 Districts:2	

District Level: In the office of District CMO/District Magistrate

Name of the Staff	**No. of Staff**	**Terms of Reference**
District Coordinator	1 per District	**Annexure 1.**
Administrative Assistant cum Data Entry Operator	1 per District	

Steps for implementation of the Act

By the Central Government

- Draft Model State Rules under Section 54 circulated to implementing State for guidance.
- A **survey** of clinical establishments in 61 districts of 11 States/UTs was done to access the ground situation of availability of infrastructure and manpower in different categories of Clinical Establishments in order to take informed decision while prescribing minimum standards. Report is available on the website.
- Application Forms and Certificate for provisional and permanent registration completed. [**Annexures 2**]
- Dedicated website (www.clinicalestablishments.nic.in) for providing information and registration
- Online registration made functional
- Develop all policy guidelines, minimum standards, Standard treatment Guidelines etc.
- Nodal Officers identified in the state and Suggested Terms of reference of additional staff (Coordinators & Data Entry Operator circulated)
- Secretariat for National Council set up
- Budget for implementation is provided through National Health Mission State PIP, as per norms.
- **Achievements with respect to various mandates of Central Govt./National Council for Clinical Establishments are as given in table as under:**

Mandate	Achievements
Categorization & Classification of Clinical Establishments	Completed and at **Annexure 3.**
Standard template for Minimum standards	Completed and broad template at **Annexure 4.**
Development of Minimum Standards for Clinical Establishments	Completed and The List at **Annexure 5.** • 35 specialties/ super-specialties • Other major General categories (allopathic) • 7 categories of AYUSH
Information & Statistics to be provided by Clinical Establishments	Formats Completed and at **Annexure 6.** 1. OPD Form 2. IPD Form 3. Lab and Imaging
Fixing of range of rates & charges	Completed and at **Annexure 7.** • List of Medical Procedures • Standard Costing Template
Standard Treatment Guidelines(STGs)	STG's for 215 medical conditions belonging to 21 Clinical Specialities and AYURVEDA

	Template of STG at **Annexure 8.** List of STG at **Annexure 9.** STGs of Programmes complied and The list is at **Annexure 9.**
Providing technical assistance and financial resources	1. Advocacy cum training workshops at state level Guideline at **Annexure 10.** 2. Training Site for practice 3. Web Based Training Module 4. Frequently Ask Question 5. Help email for providing assistance help.ceact2010@nic.in 6. Assistance through telephone 7. Receiving and responding Feedback

Financial provision through National Health Mission annual State Programme Implementation Plan (PIP)

Provision is for States and Districts for implementation of provisions of Clinical Establishments Act

The request for funds will be reflected in the Annual State PIP under NHM which will be approved by the Government of India. The fund will be released to States/UTs and handed over to respective State Council for clinical establishment for the State and District Registering Authority for the District to carry out the activities as envisaged in the operational guidelines. Funds released from State to District Regulatory Authority would inter alia include funds to cover the entire district. The statement of expenditure (SOE) and utilization certificate (UC) as per GFR shall be submitted in prescribed formats by CMO/District Health Officer.
The State and district are responsible for maintenance of accounts, release of funds, expenditure reports, utilization certificate and audit arrangements. Norms of funding shall be as per table given under:

Norms for Funding for States with less than 15 districts

	State/UT Level State/UT Level	**District level**
Coordinator	1x Rs.50000	1x Rs.30000
Administrative Assistant cum Data Entry Operator	1x Rs.10000	1x Rs.10000
Computer and Printer (first year)	1x Rs.50000	1x Rs.50000
Meeting	Meeting of State and UT Council 6x Rs. 5000	Meeting of District Registering Authority 6x Rs. 3000
Workshop for dissemination and Capacity Building	6x Rs.50000	5x Rs.30000
Operational Expenses	Rs.150000	Rs.100000

Norms for Funding for States having more than 15 districts

	State/UT Level State/UT Level	District level
Coordinator	2x Rs.50000	1x Rs.30000
Administrative Assistant cum Data Entry Operator	2x Rs.10000	1x Rs.10000
Computer and Printer (first year)	2x Rs.50000	1x Rs.50000
Meeting	Meeting of State and UT Council 6x Rs. 5000	Meeting of District Registering Authority 6x Rs. 3000
Workshop for dissemination and Capacity Building	12x Rs.50000	5x Rs.30000
Operational Expenses	Rs.300000	Rs.100000

Steps to be taken for implementation of the Act by the States

State/UT who have adopted the Act

- Formulate and Notify State Rules under Section 54 of the Act
- Constitute & notify the State/UT Council for Clinical Establishments
- Constitute & notify District Registration Authority(DRA) for each district of the state
- Identify a Nodal officer with a team at the state level for the implementation of the provisions of the Act
- NIC shall allocate passwords for DRAs and State Council for starting online registration
- Seek Funds through State NHM PIPs and ensure inclusion of the same.
- Appoint Contractual Staff as norms
- Take steps to publicise through newspaper advertisement, orientation and sensitisation workshops for all stakeholders.
- Implement procedure for Registration & Regulation as per Act. Begin the process of provisional registration (online) and permanent registration after notification of Minimum Standards
- Ensure that the time lines of the process of registration as laid down under the Act are adhered to
- Disseminate the Act, Rules, Minimum Standards, STGs, etc. at various levels and among stakeholders
- Share monthly progress report with the National Council Secretariat as per checklist (Annexure).

By the States who have not adopted the CEA

❖ ***States Not Having Own Legislation*** for regulating clinical establishments.

Adopt the CEA 2010 by passing a resolution in the state assembly under clause (1) of article 252 of the Constitution.

❖ ***States Having Own Legislation*** for regulating clinical establishments.

Repeal the Existing Act and Adopt the CEA 2010 by passing a resolution in the state assembly under clause (1) of article 252 of the Constitution.

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.
- Provisional registration is on 'as is where basis' is.
- Permanent registration is subject to fulfilment and adherence to minimum standards prescribed for that category of clinical establishments.
- The registration 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 proforma along with prescribed fee to be made to district registering authority (i.e. District Health Officer / Chief Medical Officer of concerned district).

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 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 six months from the date of notification of the standards, for clinical establishments which came into existence after standards have been notified.

Inspection:

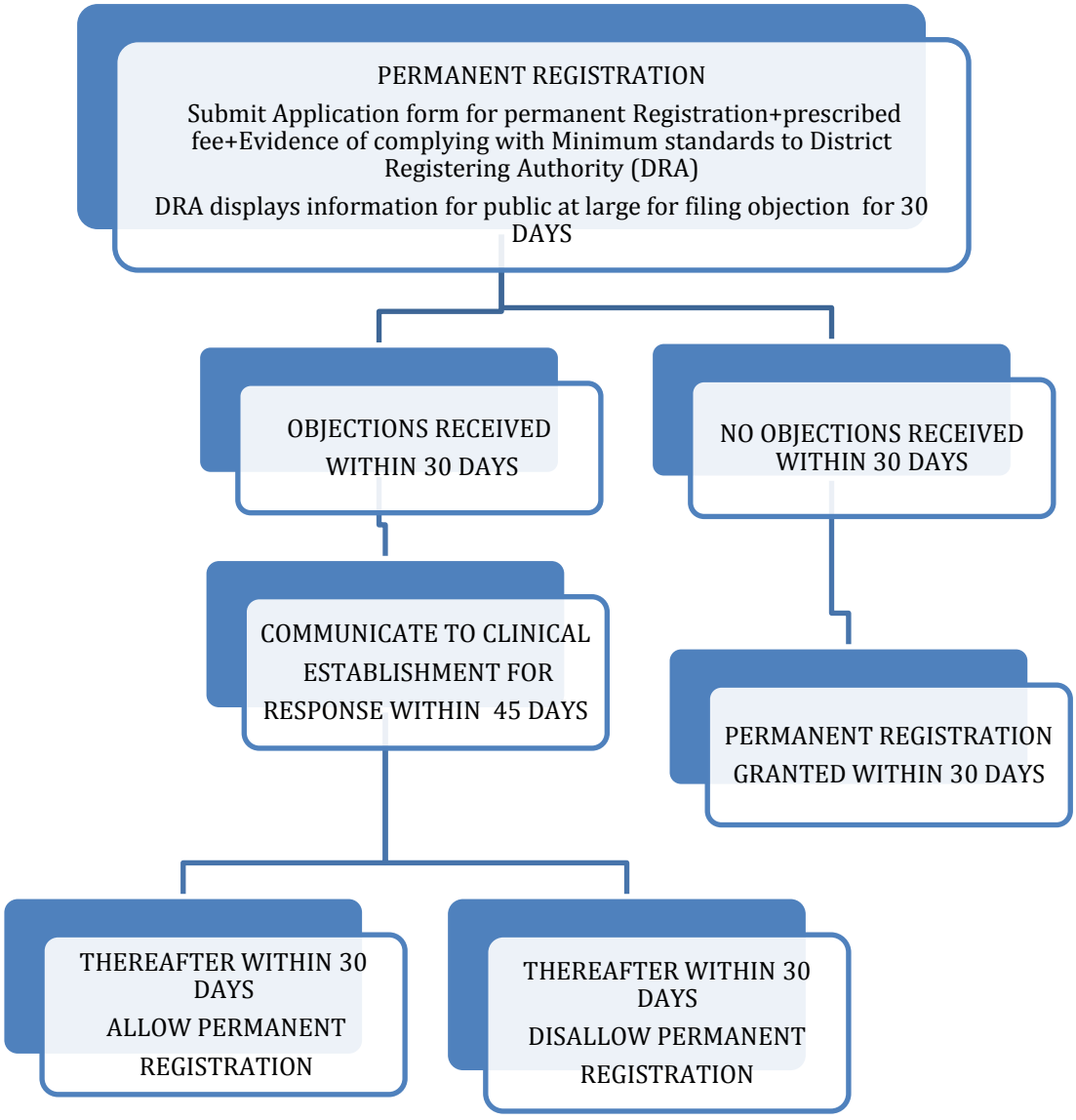
The registering authority may authorise an inspection or an inquiry of any registered clinical establishment to be made by a **multi-member inspection team**. **A show cause notice** may be issued if the authority feels that a clinical establishment is not complying with the conditions of its registration.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

The procedure for Permanent Registration is as under:



Check List regarding Status of Implementation of the Clinical Establishments Act (CEA) in The State/District

Where clinical establishments Act CEA 2010 is Applicable

- Whether you have included budget for implementation of CEA in the PIP of your state/UT for the financial year 2015 – 16.
  Yes/ No

If yes details of component wise budget asked for in the PIP proposal:

- Budget received (Yes/No):_____.
- If Yes, The amount of Money allotted, source, utilized and balance out of the money that was allocated through NHRM for implementation of CEA.
  Utilization Certificate and SOE submitted:

S. No.	Year	Allotted	Source (NRHM / Programme/ State Govt./ Registration Fee	Budget Utilized	Balance (at the end of Financial Year)	Utilization Certificate and Statement of Expenditure Submitted (Yes/No) Please provide a copy
1.	2015 – 16					
2.	2016 – 17					

- Notification of State Rules under Section 54 of the CEA,2010 (Yes/ No):
  _____
  If yes kindly Provide Date of notification: _____ (Please provide a signed copy, if not provided earlier).
  If not notified, Reasons _____.
  Please provide/annexe details of Registration Fee (category-wise) for clinical establishments:

- Has the State / UT council been notified (yes/ No): _____
  If yes kindly Provide copy of notification and details of the members and their organisations_____.Number and Date of meetings held: _____.
  If not notified, Reasons _____.

- Constitution & notification of District Registration Authorities in all districts (yes/ No): _____.
  - If yes kindly Provide copy and dates of notification giving details of members and their organisations _____.

- No. of District where Notification issued and mention name of District: _____.
- If not notified, Reasons _____.

❖ Whether the process of provisional registration started online/ offline(Yes/ No):
- If No, give reasons._____.
- If started online kindly provide details regarding the number and types
- If started offline Action taken for starting online including timeline.

❖ No. of Allopathic Clinical Establishments registered (Online/ Offline), please provide **category wise detail** as per provisional registration format specifically including Laboratories / Imaging Centre
- No. registered Online: ____
- No. registered Offline:____

❖ Details, number of AYUSH Clinical Establishments category and system of medicine wise
- No. registered Online: ____
- No. registered Offline:____

❖ Nodal officer with a team at the state level for the implementation of the provisions
Of the Clinical establishments Act (Yes/No): _____.
if Yes kindly provide
- Name:
- Designation:
- Postal address:
- Telephone No. and Fax:
- Mobile No:
- Email:

Details of personnel appointed, infrastructure provided and action taken for the implementation of the CEA, 2010

❖ State Level Coordinator (Yes/ No): _____
If yes kindly provide Number of Coordinators in place and details of each as per parameters given below:
- Name:
- Designation:
- Telephone No.:
- Mobile No:
- Email:

❖ State level cell or office with computer (Yes/No): _____

❖ No. of Data Entry Operators at State level_____

❖ District Level Coordinator (Yes/ No): _____
If yes kindly provide Number of Districts where Coordinators are in place and details of each as per parameters given below:
- Name:
- Designation:

- Telephone No.:
- Mobile No:
- Email:

- District level cell or office with computer and Data Entry Operators (Yes/No): _____.
- No. of Districts where Data Entry Operators are in place
  - If yes provide details.
- Disseminate the CEA and Rules at various levels and among stakeholders, no. & date of Meetings held no. &date of workshops held.
  - State/UT Level:
  - District level:
- Trainings organized (Yes/No):_____.
- Fee Charged for provisional Registration (Yes/No):
  If yes, give details:
- Share monthly progress report with the MOHFW on the status of the implementation of the CEA 2010(Yes/No):_____.
- Any other information or details

Details of Violations of the Act (Month Wise and details of violations) and Action taken

- **Number: _____.**
- **Details: _____.**

Complaints received (Month Wise)

- **Number: _____.**
- **Details: _____.**

And Court cases (current)

- **Number: _____.**
- **Details: _____.**