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A background note on
Clinical Establishments (Registration and Regulation) Act, 2010

The Clinical Establishments (Registration and Regulation) Act (CEA), 2010 was enacted by the Parliament in August 2010. Although public health and hospitals are constitutionally under the authority of state governments in India, this regulation was drafted and passed by the Parliament under article 252, clause (1) of the Constitution. Arunachal Pradesh, Himachal Pradesh, Sikkim, and Mizoram passed resolutions requesting the central government to draft this Act to regulate clinical establishments. The Act came into effect in March 2012 in these 4 states and 6 union territories in 2012, and has since been adopted by 6 other states. The central government recommends that all states adopt the CEA, 2010 or a similar Act in individual states. The central Act is not legal binding on the states who have not adopted it, and are free to draft their own legislation and implement it.

The central objective of the CEA, 2010 is to *"provide for the registration and regulation of clinical establishments with a view to prescribe 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."*

A Closer Look at CEA, 2010

The Clinical Establishments (Registration and Regulation) Act designed by the central government has several salient features detailed below in Table 1.

Table 1: Salient features of Clinical Establishments (Registration and Regulation) Act, 2010

'Clinical Establishments' covered	- Includes any institution offering services, diagnostic or treatment facilities caring for illness, injury, deformity, abnormality, or pregnancy; whether administered or maintained by any person, groups, or corporations. - Includes clinical establishments owned, controlled, or managed by the government, department of the government, public or private trust, local authority, or single doctor. - Excludes clinical establishments owned, controlled, or managed by the Armed Forces.
Systems of medicine covered	Allopathy; Ayurveda, Yoga, Unani, Siddha, Homeopathy (AYUSH); Naturopathy; or any other system of medicine recognized by the Central Government.
Standards established	Establish minimum standards of facilities, services, personnel,

	and maintenance of records and reporting to be fulfilled at different categories of clinical establishments.
Registration Procedure	Article 11: *"No person shall run a clinical establishment unless it has been duly registered in accordance with the provisions of this Act."* - Provisional registration for a period of 12 months to be issued within 10 days of submitting an application to the authorized district registering authority (without inquiry). - Registration Certificate to be displayed in a conspicuous place at the clinical establishment. - Permanent registration application to be submitted 1 month prior to end of provisional registration, along with information regarding conformity to minimum standards. - Information provided by clinical establishments to be displayed to the public for 30 days to allow for filing objections. - If no objections, application for permanent registration will be processed. If objections are received, they are communicated to the establishments with a response period of 45 days, and the application processed within 30 days after receiving a response. Article 28: *"Permanent registration shall be granted only when a clinical establishment fulfils the prescribed standards for registration by the Central Government."* - Permanent registration for a duration of 5 years. - At the end of the prescribed period, the authority pass an order allowing/disallowing permanent registration of the clinical establishment. - No provisional registration will be issued after 2 years from the date of notification of standards of this Act, or a period of 6 months for establishments which were set up after notification of standards.
Cancellation of registration	Conditions for cancellation of registration include: - Conditions of registration not being complied with. - Persons entrusted with management of clinical establishment convicted of an offense punishable under this Act. If either of the above conditions are met, a show cause notice is issued on why its registration should not be cancelled within three months. After cancellation of registration, the authority may restrain the establishment from operating if there is imminent danger to the health and safety of patients.
Inspection of registered clinical establishments	- The authority or authorized officer shall have the right to inspect any registered clinical establishment, its building, laboratories, equipment, and work done by the establishment. - Multimember inspection teams to conduct inspections, and results of inspection to be communicated to the clinical establishment with advice on actions to be taken. - The act gives the authority the power to enter any clinical

	establishment suspected of not having registration and carry out a search at a reasonable time after giving notice of intention to do so.
Register of clinical establishments	- The authority is required to establish, compile, publish, and maintain a digital registry of clinical establishments registered under its authority. - State and Central governments shall also maintain a digital registry of all registered clinical establishments.
Penalties	- Contravening the provisions of this Act can be punished with fines as follows: Rs. 10,000/- for first time offence, Rs. 50,000/- for second time offence, and upto Rs. 5,00,000/- for subsequent offences. - Clinical establishments who do not register with the authority under the Act can be liable to a fines as follows: Rs. 50,000/- on first contravention, upto Rs. 2,00,000/- for second contravention, upto Rs. 5,00,000/- for any subsequent contravention. - Persons wilfuly disobeying of directions of Act, obstruction or refusal of information can be liable to a penalty upto Rs. 5,00,000/- - Persons contravening provisions of the Act or its rules resulting in deficiencies not posing imminent danger to the health and safety of any patient (and can be rectified in reasonable time) can be fined upto Rs. 10,000/- - The state council for clinical establishments can send a certificate specifying the fine amount to the Collector of the relevant District to recover the fine.
Care of emergency patients	*"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 condition of any individual who comes or is brought to such clinical establishment."*
Cost of services	- The CEA proposes to establish ranges of rates for all services provided by health clinics, accounting for establishments providing higher levels of care. - These ranges currently apply to the public patients covered by the national health insurance schemes. Under the CEA, the regulated prices would also be applicable for private patients. - It is also mandatory for all clinical establishments to prominently display the rates of all the services provided in their establishments.
Establishing treatment guidelines	- The central CEA established patient management guidelines for all health conditions. These guidelines are intended to be followed by all healthcare providers for the clinical management of patients.

The structure proposed by the Clinical Establishments (Registration and Regulation) Act for implementing and enforcing the Act includes the establishment of a National Council for Clinical Establishments, State (or Union Territory) Council for Clinical Establishments, and District

Registering Authority. A schematic representation of the proposed organizational structure is depicted below in Figure 1.

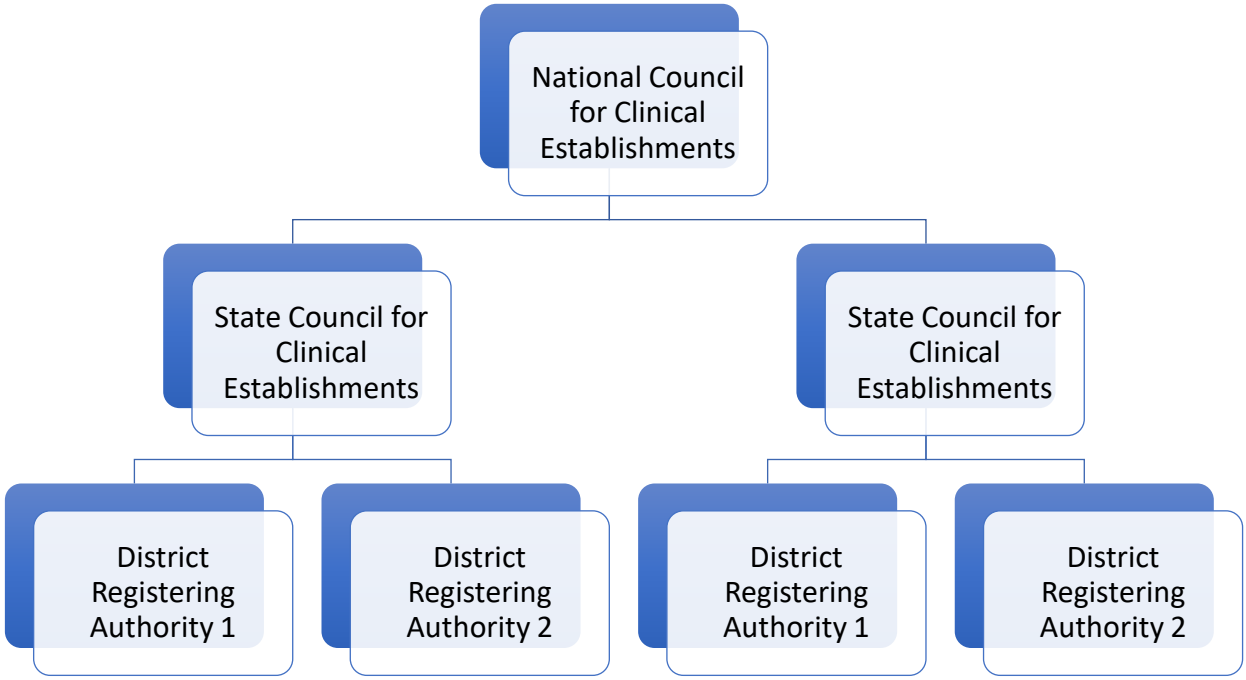

Figure 1: Schematic of Organizational Structure for Implementation and Enforcement of CEA, 2010

Implementation of CEA, 2010 Across India

The Clinical Establishments (Registration and Regulation) came into effect in 4 states and 6 union territories in India in 2012. Since then, 6 other states have adopted the act, while 3 states are in the process of adopting it. 8 more states are either enacting separate legislation for clinical establishments or have pre-existing legislation.

The Director General of Health Services, Ministry of Health & Family Welfare has recommended that states in India gradually adopt this Act in order to provide overall improvement in the quality of healthcare services in the country. Even states with similar legislation are advised to repeal existing Acts and adopt a Clinical Establishments Act guided by the terms of CEA, 2010.

Issues with CEA, 2010

There are several terms of the central Clinical Establishments (Registration and Regulation) Act, 2010 that have received strong opposition for stakeholders such as the Indian Medical Association (IMA), diagnosticians, and the National M.Sc. Medical Teachers Association. The issues brought up by stakeholders previously are listed below:

1. The minimum standards established by the act might make it unviable for small and medium-size clinical establishments to provide healthcare.

2. Government regulation of rates for services is seen as restrictive to the growth of the private healthcare sector. While pre-determined charges for services provided to patients covered under the national health insurance schemes are acceptable, private providers would prefer to have complete authority over the rates of services provided to self-paying patients and those covered by private health insurance.
3. Private healthcare providers want the onus of safe transportation of emergency cases and their clinical management costs to be borne by the government. In addition, a revision is sought of article 12(2) mandating the stabilizing of emergency cases at clinical examinations.
4. The legal standing of the grievance redressal mechanism suggested by the CEA is under scrutiny. It is seen by the IMA as an potential source of unnecessary stress and harassment for doctors.
5. The penalty rates proposed in the CEA are considered excessive by healthcare providers.
6. Instead of the standards established by CEA for maintenance of records and their reporting in order to better inform public health initiatives, it is suggested that the surveillance and data collection by the Integrated Disease Surveillance Program is improved.
7. The Act also establishes clinical management guidelines for each health condition. This was an effort made by the central government to reduce the practice of inappropriate use of diagnostic tests, overdiagnosis, and overtreatment. However, these guidelines are seen by some stakeholders to be limiting the clinical freedom of doctors.

Discussion among state-level stakeholders is required on these issues to inform the development of a more suitable legislation for the needs of the state.

Need for Clinical Establishment Legislation in Andhra Pradesh and Telangana

The erstwhile state of Andhra Pradesh adopted the AP Private Medical Establishment Regulations and Registration Act in 2007 to regulate private clinical establishments practicing modern medicine (allopathy). However, the implementation has been seen to be patchy and ineffective. More recently (March 2017), the Telangana state Legislative Council approved the adoption of the Clinical Establishment Act, 2010 in the state. However, the state rules and specific details of the Act to be adopted remain to be discussed and drafted. In this context, it is essential for the different stakeholders involved to engage in productive discussions and draft sound recommendations to the state government.

In the current context, it is crucial to implementation a suitable legislation to satisfy several objectives. Firstly, there is a need for improved monitoring and transparency in order to restore and enhance trust between the general public and clinical establishments. Secondly, such an institutional mechanism should not degenerate into an intrusive licensing organization with overemphasis on

regulation, or become a breeding ground for corruption. Lastly, as far as practical, such a mechanism should be under the broad supervision of medical experts and healthcare professionals instead of government departments. This would enable informed judgements to be made when dealing with complex issues.

With these objectives in mind, it is necessary to draft an appropriate legislation and duly consider the following issues:

1. Establish sound registration mechanism for all healthcare institutions, with clear conditions for cancellation of registration.
2. Improve transparency in the healthcare sector through self-disclosure by clinical establishments. Make this information available to the public to bridge the information asymmetry currently present in the sector.
3. Establish monitoring mechanism for clinical establishments under the purview of professional bodies.
4. Composition of professional bodies at city/district level and the state level.
5. Effective accountability mechanisms to build accountability in the healthcare sector.

An essential requirement for the new legislation is to avoid strict regulations that would make the healthcare sector a 'licence raj'. The implementation of such a legislation would not only receive be counterproductive, but also receive strong opposition from stakeholders and be difficult to implement as has been seen in 4 of the 18 states who have adopted the CEA, 2010. Hence, over-regulation of the sector needs to be avoided while simultaneously empowering the public to make informed healthcare decisions with the help of quality information about clinical establishments.