



Clinical Establishments Law

- *Towards Transparency and Informed Consumers*

Foundation for Democratic Reforms
17 & 19 August , 2017



भारत का राजपत्र The Gazette of India

असाधारण
EXTRAORDINARY
भाग II — खण्ड 1
PART II — Section 1
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

नई दिल्ली, बुध्स्तिवार, अगस्त 19, 2010 / श्रावण 28, 1932
NEW DELHI, THURSDAY, AUGUST 19, 2010 / SRAVANA 28, 1932

पृष्ठ संख्या दी जाती है जिससे कि यह अलग संकलन के रूप में रखा जा सके।
Given to this Part in order that it may be filed as a separate compilation.

MINISTRY OF LAW AND JUSTICE
(Legislative Department)

New Delhi, the August 19, 2010/Sravana 28, 1932 (Saka)

Parliament received the assent of the President on the
published for general information:—

ESTABLISHMENTS (REGISTRATION AND
ATION) ACT, 2010

Legal Standing of Clinical Establishments Act, 2010

- Enacted by the Parliament under Article 252(1) of the Indian Constitution.
- States retain the right to adopt the central Act, or create a State Act independently.

Central Government Act

Article 252 in The Constitution Of India 1949

252. Power of Parliament to legislate for two or more States by consent and adoption of such legislation by any other State

(1) If it appears to the Legislatures of two or more States to be desirable that any of the matters with respect to which Parliament has no power to make laws for the States except as provided in Articles 249 and 250 should be regulated in such States by Parliament by law, and if resolutions to that effect are passed by all the House of the Legislatures of those States, it shall be lawful for Parliament to pass an Act for regulating that matter accordingly, and any Act so passed shall apply to such States and to any other State by which it is adopted afterwards by resolution passed in that behalf by the House or, where there are two Houses, by each of the Houses of the Legislature of that State

Provisions Under Central Act

Diagnostic and treatment facilities

Public and private healthcare facilities

Modern Medicine, Ayurveda, Unani, Siddha, Homeopathy

Establishments covered

Permanent Registration (5 years)

Provisional Registration (12 months)

Mandatory registration

Service availability

Record maintenance

Facilities

Personnel

Minimum standards

Clinical Establishments (Registration & Regulation) Act, 2010

Maintain Registry

District

State

National

Regulates cost of services

Establishes patient management guidelines

Mandatory stabilization of emergency cases

Accountability mechanisms

Inspection of establishments

Penalties

Registration cancellation

Key Issues Related to CEA, 2010

1. **Minimum standards** unviable for small and medium-size establishments.
2. **Regulation of rates** might restrict the growth of the private healthcare sector.
3. **Mandatory stabilization** of emergency cases may not be practically feasible for all establishments.
4. **Grievance redressal mechanism** a potential source of harassment for doctors.
5. **Mandatory establishment of information systems** may not be practically feasible for all establishments.
6. **Strict clinical management guidelines** limit the clinical freedom of doctors.
7. **Limited administrative capacity** to implement Act locally.

Guidelines for Drafting Legislation For Clinical Establishments

3 main guidelines to follow:

1. Transparency and disclosure of information by all categories of clinical establishments;
2. Institutional mechanism should not degenerate into corrupt licensing body;
3. Monitoring mechanism must be supervised by reputed, competent healthcare professionals capable of making informed judgements.

Broad Components of (draft) Informed Healthcare Act

- Mandatory registration and self-disclosure by clinical establishments.
- Online Register of disclosed information for empowerment of patients:

Infrastructure	Services	Personnel and their qualifications
Rates of services	Accreditations	Quality control/performance data

- Establish credible monitoring mechanisms under the supervision of professional bodies and practicing healthcare professionals:
 - Inspection upon credible complaint
 - Notification of deficiencies
- Designing effective redressal mechanisms to build accountability in healthcare sector:
 - Penalties and suspension of registration
 - State-level body to address institutional malpractice or non-adherence to guidelines

Specific Components Requiring Input

1. *Should small clinical establishments be included in the new legislation?*
2. City/district and state-level monitoring bodies:
 - *What process can we follow to select members for this body?*
 - *How do we ensure that these bodies are composed of credible people?*
3. Regular publication of clinical guidelines by state-level body:
 - *Are you in favour of this?*
 - *How regularly should they be updated?*
 - *How strictly should their implementation be monitored?*

Specific Components Requiring Input

4. Penalties for non-registration, non-disclosure, falsification of information and non-adherence to guidelines. Includes monetary and non-monetary penalties:

- *Is the framework acceptable?*
- *Can we improve on this?*

5. Laboratories and diagnostic centers:

- *What specific components should we monitor under this legislation?*
- *What quality control measures can we monitor?*

6. Establish research wing under State-level body to conduct inter-state and international comparisons of performance:

- What is your perspective on this function?