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Pharmacy Law & Ethics
Chapter 16 : Clinical Establishment Act and Rules

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Chapter 16
Clinical Establishment Act and Rules

- The Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Central Government to provide for registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them.
- The Act has taken effect in the four States namely; Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, and all Union Territories except the NCT of Delhi since 1st March, 2012 vide Gazette notification dated 28th February, 2012.
- The States of Uttar Pradesh, Uttarakhand, Rajasthan, Bihar, Jharkhand, Assam and Haryana have adopted the Act under clause (1) of article 252 of the Constitution.
- The Clinical Establishment Rules are a set of guidelines and regulations issued by the government of India to regulate the functioning of clinical establishments across the country.

Objectives

- To improve the quality of healthcare by creating the standards of Health care facilities which are required for all types of Health care establishment.
- To prevent unqualified practitioners by an obligatory registration system.
- To create a national state and district level digital registration of clinical establishment.

Procedure for registration

- The owner of Establishment is responsible for registration
- The registration can be done in following ways:
- In person by visiting office of District CMO (Chief medical Officer)
- By post by sending filled in application along with proof of payment of fee
- Online by visiting website www.clinicalestablishments.nic.in

Information required during registration for clinical establishment

- Details of establishment categories
- Address
- Medical facilities
- Details of owner
- Details of person in charge (registration number)
- Details of other medical and paramedical staffs with registration number
- Types of facilities are provided
- Facilities for disposal of medical wastes
- Fire fighting system

Renewal of Registration

- Provisional Registration is valid for 1 year and renewal application should be applied before 30 days of expiry.
- Permanent Registration is valid for 5 years and renewal application should be applied before 6 months of expiry.

Penalties for Non registering a clinical establishment

- On first conviction -- up to fifty thousands.
- On Second Conviction -- up to one lakh rupees.
- On subsequent conviction -- may extend to five lakh rupees.

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