

# Chapter-17

## Clinical Establishment Act and Rules – Aspects related to Pharmacy

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### Clinical Establishment Act and Rules – Aspects related to Pharmacy

#### Introduction:

- 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.

#### Here are some lists of Clinical Establishment Rules:

1. **The Clinical Establishments (Registration and Regulation) Act, 2010:** This is the primary legislation governing clinical establishments in India. It provides for the registration and regulation of all clinical establishments, including hospitals, clinics, and diagnostic centers.
2. **Minimum Standards of Medical Education and Training Regulations, 2020:** These regulations prescribe the minimum standards for medical education and training in India. They also specify the criteria for the recognition of medical colleges and institutions.
3. **National Accreditation Board for Hospitals & Healthcare Providers (NABH) Standards:** These standards were developed by the Quality Council of India in consultation with various stakeholders, including healthcare providers, experts, and patient groups. They provide a framework for assessing the quality and safety of healthcare services in India.
4. **Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002:** These regulations set out the code of conduct and ethics for medical practitioners in India. They provide guidelines for professional behavior, patient care, and confidentiality.



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5. **Consumer Protection Act, 2019:** This is a comprehensive law that protects the rights of consumers in India. It provides for the establishment of consumer courts and the redressal of consumer grievances, including those related to healthcare services.
6. **Drugs and Cosmetics Act, 1940:** This act regulates the import, manufacture, and sale of drugs and cosmetics in India. It sets out the standards for the quality, safety, and efficacy of these products.
7. **Indian Nursing Council Act, 1947:** This act governs the nursing profession in India. It provides for the establishment of the Indian Nursing Council and the regulation of nursing education and practice.

The Clinical Establishment Act, pharmacies are classified as clinical establishments and are required to be registered with the relevant authorities.

The Act lays down certain rules and regulations that pharmacies need to follow to ensure the safety and well-being of their patients. Some of the key aspects related to pharmacy under the Clinical Establishment Act are:

1. **Registration:** The Act mandates that all clinical establishments, including pharmacies, must be registered with the appropriate regulatory authority. The registration process includes providing information on the ownership, location, infrastructure, and services offered by the pharmacy.
2. **Qualifications and Training:** The Act specifies that the pharmacists working in a pharmacy must possess the necessary qualifications and training as per the Pharmacy Council of India guidelines. The pharmacists are also required to renew their registration every five years and undergo regular training to stay updated with the latest developments in the field of pharmacy.
3. **Quality of Drugs and Services:** The Act mandates that pharmacies must ensure the quality of drugs and services offered to patients. This includes proper storage of medicines, maintaining proper records of medicines dispensed, and ensuring that the medicines are not expired or substandard.
4. **Patient Safety:** The Act lays down guidelines for patient safety in pharmacies. This includes ensuring that the prescriptions are legible and accurate, maintaining patient confidentiality, and providing adequate information on the use of medicines to patients.
5. **Grievance Redressal:** The Act provides for a mechanism to address grievances of patients and their relatives. The pharmacy is required to have a complaint redressal mechanism in place, and patients can approach the relevant authorities in case of any complaints.

