Clinical Establishments (Registration and Regulation) Act, 2010

Overview

- The **Clinical Establishments (Registration and Regulation) Act, 2010** is a central legislation enacted to provide a legal framework for the registration, regulation, and standardization of all clinical establishments across India.
- The Act aims to ensure uniformity in healthcare services and promote quality, transparency, and accountability in the medical sector.

Purpose and Objectives

- To ensure that all clinical establishments adhere to minimum standards of facilities and services.
- To promote transparency, accountability, and ethical practices in the delivery of healthcare.
- To establish a system for registration and regulation of clinical establishments.
- To standardize healthcare services across both public and private sectors.

Applicability

- The Act is applicable to both government and private clinical establishments and covers a wide range of healthcare facilities, including:
    - Hospitals
    - Nursing Homes
    - Clinics
    - Diagnostic Laboratories
    - Blood Banks
    - Pharmacies (operating within a clinical establishment)
- The Act plays a crucial role in improving the overall quality of healthcare services in India by ensuring that establishments meet prescribed norms and deliver services responsibly.

Aspects related to Pharmacy

1. Applicability to Hospital Pharmacies

- If a hospital or clinic has an in-house pharmacy, it is considered part of the clinical establishment.
- The pharmacy must comply with:
    - Drug storage conditions

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- Qualified pharmacist availability
- Record-keeping
- Expiry date monitoring

2. Registration Requirement

- Every clinical establishment (including hospital pharmacies) must be registered with the District Registering Authority.
- Separate registration may be required for in-house pharmacy or dispensing unit.

3. Minimum Standards

- Pharmacies must comply with:
  - Storage conditions
  - Prescription validation
  - Trained pharmacy staff (Registered Pharmacists)
  - Dispensing standards
- Use of computerized inventory systems is recommended.

4. Display of Information

- Pharmacies must display:
  - Name of pharmacist on duty
  - License and registration details
  - Patient rights and drug pricing (MRP)

5. Records and Documentation

- Maintain records of:
  - Dispensed medications
  - Narcotic and psychotropic substances (as per NDPS Act)
  - Adverse Drug Reaction reports (if applicable)
  - Expiry management logs

6. Standard Treatment Guidelines

- Encourage rational drug use in line with essential drug lists and treatment guidelines.

7. Inspections and Penalties

- Drug Inspectors or Health Officers may inspect for compliance.

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- Non-compliance may lead to:
  - Suspension or cancellation of registration
  - Monetary penalties
  - Legal proceedings

Link to Other Laws

- **Complementary to:**
  - Drugs and Cosmetics Act, 1940
  - Pharmacy Act, 1948
  - Biomedical Waste Management Rules, 2016
  - Narcotic Drugs and Psychotropic Substances (NDPS) Act

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