D.PHARM • SECOND YEAR

Pharmacy Law & Ethics

CHAPTER 16

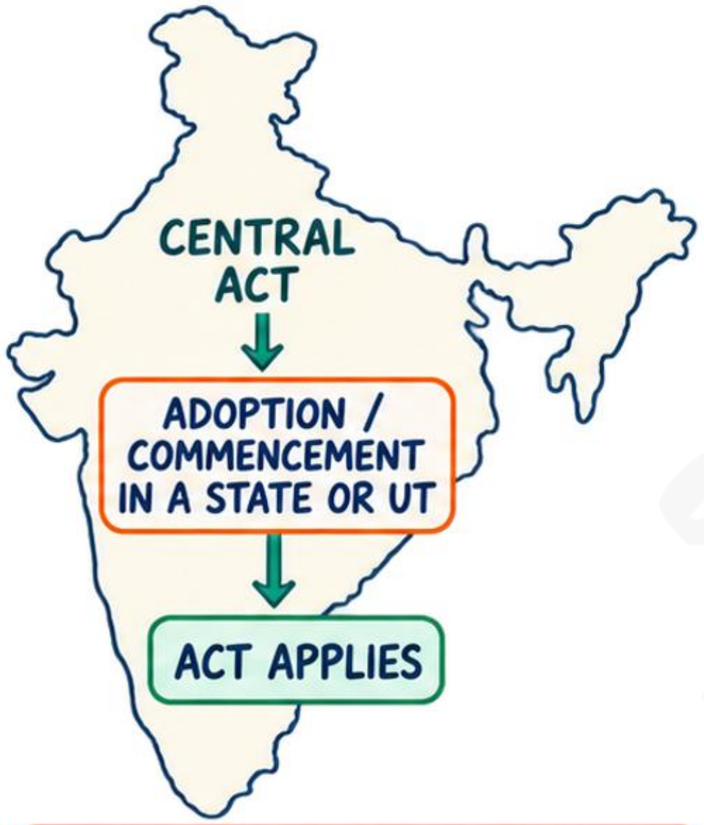
Clinical Establishments Act and Rules



ENGLISH CHAPTER NOTES

DIPLOMA IN PHARMACY

CLINICAL ESTABLISHMENTS (REGISTRATION AND REGULATION) ACT, 2010

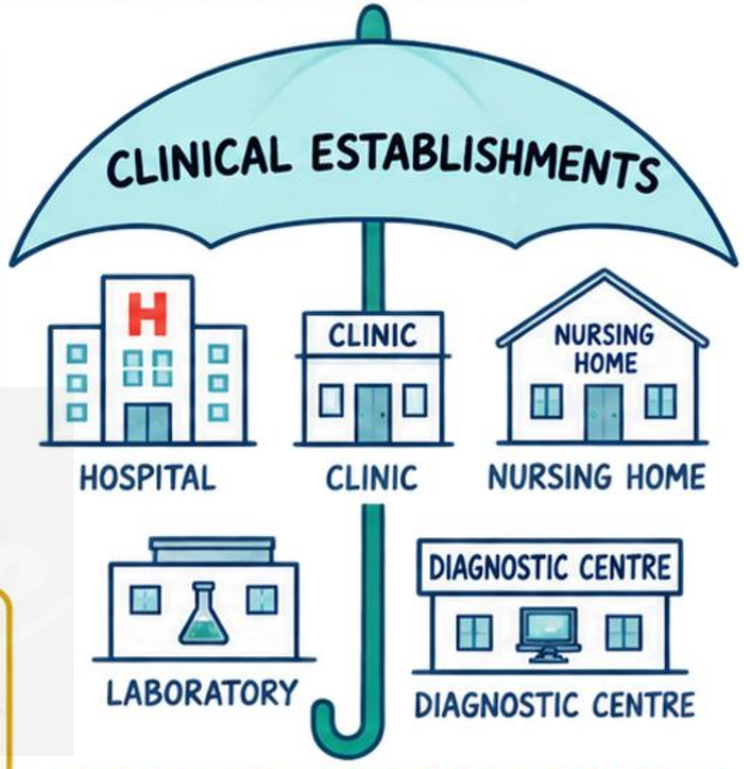


OVERVIEW

Act No. 23 of 2010 provides for registration and regulation of clinical establishments and for prescribed minimum standards of facilities and services.

Main aims: better quality and patient safety • transparency and accountability • an authorised registry • useful health statistics • fewer unqualified establishments.

The Clinical Establishments (Central Government) Rules, 2012 support implementation; State / UT rules and notifications also matter.



WHAT IS A CLINICAL ESTABLISHMENT?

A place providing diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in a recognised system of medicine.

It includes hospitals, maternity homes, nursing homes, dispensaries, clinics, sanatoria, laboratories and diagnostic centres, including single-doctor clinics.

Public and private establishments are covered. Establishments owned, controlled or managed by the Armed Forces are excluded.



Establishments owned, controlled or managed by the Armed Forces are excluded.

IMPORTANT – WHERE DOES IT APPLY?

The Central Act does not automatically apply uniformly in every State. It applies where it has commenced or has been adopted under Article 252(1) of the Constitution.

Always check the latest State / UT notification and category-specific commencement before deciding legal applicability.

REGULATORY STRUCTURE

NATIONAL COUNCIL
recommends classification and standards

→

STATE / UT COUNCIL
supports implementation

→

DISTRICT REGISTERING AUTHORITY
registers and regulates establishments in the district.

ASPECTS RELATED TO PHARMACY

REGISTRATION PATH

The owner is responsible for registration with the District Registering Authority. No covered clinical establishment may operate without registration.

PROVISIONAL REGISTRATION → OWNER → APPLICATION + PRESCRIBED FEE → SELF-DECLARATION → PROVISIONAL CERTIFICATE

PROVISIONAL REGISTRATION: application + prescribed fee + self-declaration; ordinarily granted without prior inquiry or inspection.

PERMANENT REGISTRATION → CATEGORY STANDARDS NOTIFIED → EVIDENCE / INSPECTION → COMPLIANCE → PERMANENT REGISTRATION

PERMANENT REGISTRATION: follows category classification, notified minimum standards and proof of compliance; renewal and fees follow applicable State / UT rules.

CONDITIONS FOR REGISTRATION & CONTINUATION

1. Minimum standards of facilities and services.
2. Minimum qualified personnel.
3. Records, reports, information and statistics as prescribed.
4. Display facilities and rates conspicuously in the local language and English; follow applicable rate requirements and Standard Treatment Guidelines.
5. Provide, within available staff and facilities, examination and treatment needed to stabilise an emergency medical condition.



INSPECTION & ENFORCEMENT

The District Registering Authority or authorised team may inspect, seek records and issue directions. Non-compliance can lead to correction orders, monetary penalty, cancellation, or restraint where patient safety is in imminent danger.

Reasonable opportunity of being heard and appeal provisions apply.

INSPECTION
(by District Registering Authority or authorised team)

- Correction orders
- Monetary penalty
- Cancellation
- Restraint where patient safety is in imminent danger

SECTION 41 — OPERATING WITHOUT REGISTRATION

1. First contravention: up to ₹50,000.
2. second: up to ₹2,00,000.
3. subsequent: up to ₹5,00,000.

Knowingly serving in an unregistered establishment: up to ₹25,000.

LINK TO OTHER LAWS

Drugs and Cosmetics Act, 1940 & Rules, 1945

Pharmacy Act, 1948 and Pharmacy Practice Regulations

LICENCE & PERSONNEL

valid drug licence; Registered Pharmacist available as required; roles and training documented.

INVENTORY & EXPIRY

FEFO, stock reconciliation, expiry segregation, recall procedure and safe disposal.

SAFE STORAGE

labelled areas, required temperature / cold chain, restricted access, sanitation and calibrated monitoring.

RECORDS

purchases and sales / dispensing, Schedule H1 and narcotic or psychotropic records where applicable, temperature logs, expiry / return logs and ADR reports when relevant.



DISPENSING

validate prescription, select the correct medicine, label clearly, counsel the patient and prevent medication errors.

PATIENT INFORMATION

display licences, pharmacist details, rates / MRP and patient information required by applicable law.

NDPS Act, 1985 & Rules

Bio-Medical Waste Management Rules, 2016

HOW THE PHARMACY FITS

An in-house hospital pharmacy is a service within the clinical establishment. The establishment's CEA registration does not replace licences or registrations required under drug, pharmacy, controlled-substance or State laws.

A standalone retail pharmacy is not made a clinical establishment merely by selling medicines; its legal duties mainly arise under the applicable drug and pharmacy laws.

CEA authority checks establishment registration and standards; **Drug Inspector** checks drug-licence and drug-law compliance. The two roles should not be confused.

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