



Regulatory requirements for private Hospitals **Laws to be complied by private hospitals in india.**

A clinic may be defined as a place of professional practice with facilities for outdoor consultation and treatment during scheduled hours by one or more physicians and staff and equipment essential for the services provided. It may or may not have the facilities for limited investigations specific to the scope of services provided.

A large percentage of the population, in rural as well as urban areas, is dependent on private clinics and, therefore, the quality of healthcare services provided by them is very important. At present there is no system of registration of private clinics by health authorities in India. The Clinical Establishments (Registration and Regulation) Bill, 2007 is still pending in the parliament.

Presently, the operation of private clinics is being governed by the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 and certain other legislations as outlined below.

1. Registration/Requirement of Licenses

- Registration with health authorities is not mandatory for private clinics but the clinic will be subject to inspections in case of any complaints. If and whenever the Clinical Establishments (Registration and Regulation) Bill, 2007 is passed by the parliament and implemented by the states, registration of all clinics (Private/Public) of all systems of medicine will become mandatory;
- Registration with the municipal authorities (Delhi Shops and Establishments Act, 1954);
- Recognition for usage of narcotic drugs (Delhi Narcotic Drugs (Amendment) Rules, 2002);
- Authorisation for generation of Bio-Medical Waste, if treating 1,000 or more patients per month;
- Permit for procurement/usage of spirit;

- Registration under the Medical Termination of Pregnancy (MTP) Act 1971, the Pre-Natal Diagnostic Techniques (PNDT) Act, 1994, as applicable.

2. Regulations Related to Employment of Staff

- Employment of staff (Doctors, Nurses, Pharmacists) only after proper credentialing;
- Prevention of sexual harassment of women at work place (Judgment of the Supreme Court of India (SCI) in Sakshi Vs the Union of India and Others);
- Responsibility of employer for safety of employees (Delhi High Court Judgment in Ms XYZ Vs Shanti Mukund Hospital, Delhi and Punjab & Haryana High Court Judgment in Jasbir Kaur Vs the state of Punjab);
- Rules governing the employment of staff (Delhi Shops and Establishments Act, 1954);
- Immunisation / other measures for protection of staff from Occupational Health hazards.

3. Sign Boards

- Rules for the size, contents and correct place for sign boards (IMC Regulations 2002).

4. Information to be displayed at the Clinic

- Certificate of registration of clinic with the municipal authorities;
- IMC/SMC registration certificate (IMC Regulations, 2002);
- Charges for consultation and other procedures/services (IMC Regulations 2002);
- Clinic timings, closed days (Delhi Shops and Establishments Act, 1954).

5. Documents to be maintained by the Clinic

- Registration of the clinic with the municipal authorities (Delhi Shops and Establishments Act, 1954);
- Record of employment of adults, letters of employment issued and hours of work;
- Maintenance of record of patients treated (IMC Regulations 2002) and a register of medico-legal cases (MLCs);
- Maintenance of a register of medical certificates issued;
- Copies of medical certificates issued;

- Registration certificates of doctors/nurses/pharmacists with the State Medical Councils (SMCs);
- Professional qualifications (degrees/diplomas) of the staff;
- Record of consumption of Morphine (if applicable) (Delhi Narcotic Drugs Rules, 2002);
- Account of money receipts and expenses (Income Tax Act, 1961);
- Authorisation for generation of Bio-Medical Waste and record of category wise waste generated (BMW Management Rules, 1998);

6. Issue of any medical certificate, notification, document or report, which is untrue, misleading or improper is a misconduct and **punishable offence** (IMC Regulations 2002, Section 197 of Indian Penal Code);

7. Regulations Related to Treatment of Patients

- Valid consent for examination/investigation/treatment/research procedure (or informed refusal of consent), as applicable (IMC Regulations, 2002);
- Confidentiality of privileged communication, as far as permitted under the law;
- Life saving treatment of emergency cases (SCI Judgment in Parmanand Katara Vs Union of India, and The Delhi State CDRC (Consumer Disputes Redressal Commission) Judgment in the case of death of NB Sub K L Guliani);
- PNDDT Act 1994, Conduct of Euthanasia (SCI Judgment in Aruna R Shanbaug Vs Union of India & Others, March 2011), MTP Act 1971 and IPC sections 312-315, 318;
- Rules for issue of prescriptions (IMC Regulations, 2002);
- Maintenance of Medical Records of the patients treated for a period of three years and as per the format vide Appendix 3 to the IMC Regulations, 2002;
- Reporting of Medico-Legal cases to the police;
- Reporting of occurrence of occupational diseases;
- Responsibility for ensuring safety of patients (Judgment of Punjab High Court in Jasbir Kaur Vs the State of Punjab);
- Rights of patients;

- Privacy of patients during consultation, examination and treatment;
- Professional indemnity insurance cover of an appropriate amount (Insurance Regulatory and Development Authority Act, 1999);
- Laws applicable to medical negligence — Vicarious Liability, Respondeat Superior, Indian Contract Law, Tort law, Consumer Protection Act, 1986, Indian Penal Code sections (52, 80, 88, 89, 92, 93, 274-276, 284, 304-A, 336, 337, 338 and 376-D).

8. Drug and Cosmetics Act 1940, Drugs (Control) Act 1950, Narcotic Drugs and Psychotropic Substances Act 1985, Drugs and Magic remedies (Objectionable Advertisements) Act, 1954, Pharmacy Act, 1948.

9. Submission of Reports/Returns to Health Authorities

- Cases of notifiable diseases as applicable in the state (Section 371, Delhi Municipal Corporation Act);
- Report of cases of food poisoning, if required by Municipal Health Authorities (Prevention of Food Adulteration Act, 1954);
- Incidence of needle stick injuries;
- Annual report under BM Waste Management Rules, 1998 (if applicable);
- Reports on the MTPs carried out;
- Reports on the USG abdomen (abdominal ultrasonography) done on the pregnant women.

10. Safe disposal of infectious/hazardous waste generated at the clinic (BMW Management Rules, Environment Protection Act 1986, IPC Section 269, 270).

11. Prohibition of unethical activities, such as soliciting patients directly or indirectly, by a physician, a group of physicians, or by institutions or organisations by advertising, self-promotion or self-aggrandizement; use of touts for procuring patients; giving/offering or receiving rebates, gifts, commissions, cutbacks or kickbacks in return for referral or procurement of patients etc (IMC Regulations, 2002).

12. Prohibition of Smoking in Public Places Rules, 2008, Fire Safety Regulations, Financial Regulations: Income Tax Act, Value Added Tax (VAT) Act, Central Sales Tax Act, etc.

13. State laws for prevention of vandalism/violence against medical service staff and institutions.

Note: 1. All of these regulations may not be applicable to every clinic.

2. Delhi Laws quoted above may be substituted by the relevant state laws.