

ORIGINAL ARTICLE

Healthcare Regulations in India: Developing a 'Compliance Tracker' for Effective Hospital Regulatory Adherence

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Narinder Kumar, Shalini Sharma, Malvika Singh. Healthcare Regulations in India: Developing a 'Compliance Tracker' for Effective Hospital Regulatory Adherence. RFP Jr. of Hosp. Admin.; 2025 9(1): 25-31.

ABSTRACT

This article provides an in-depth analysis of the statutory requirements for hospital establishments in India, offering a detailed review of the regulatory framework governing the healthcare sector. It aims to explain the complex legal rules and regulations that hospital administrators/Medical Superintendents need to follow to stay compliant.

By addressing the key challenges encountered in adhering to these regulations and presenting practical strategies for compliance, the study underscores the critical importance of legal conformity in promoting quality healthcare delivery, ensuring patient safety, and maintaining institutional accountability.

This article also introduces a tool "Compliance Tracker" which can be used to monitor important licenses and timely registrations to various agencies. This comprehensive overview and the provided tool serves as a valuable resource for healthcare professionals and administrators, facilitating a nuanced understanding of their legal responsibilities within India's dynamic healthcare environment. This article explores key aspects of regulatory compliance in Indian hospitals, focusing on the areas outlined in Table 1.

By systematically addressing these key areas, this article aspires to serve as a valuable resource for hospital administrators, healthcare policymakers, and other stakeholders. It seeks to guide them through the complexities of regulatory

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➤ **Received:** 20-02-2025 ➤ **Accepted:** 18-06-2025



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compliance, thereby fostering an environment conducive to improved healthcare.

KEYWORDS

• Healthcare Regulations • Patient Safety • Health and Law • Regulatory Framework • Hospital Administration

INTRODUCTION

The healthcare sector in India works within a multidimensional framework of regulatory compliances these are governed by various Acts and Rules. Which forms a list of statutory requirements, hospital establishments must adhere to these statutory requirements to ensure legal accountability as well as operational efficiency and patient safety. However, these complex and often fragmented regulatory framework sometimes presents significant challenges for Hospital Administrators and/or to Medical Superintendents. Hospital administration department is not present in all healthcare institutions; consequently, their functions are typically managed by the office of the Medical Superintendent.

This paper reviewed the key regulatory compliances in Indian hospitals, offering practical insights for hospital administrators, medical superintendents, and to institutional leaders. It also highlights a tool named 'Compliance Tracker' which is developed to monitor critical regulatory requirements and ensure timely actions. The Compliance Tracker (Table 2) is based on the regulatory compliances summarised in Table 1. Compliance Tracker includes a list of essential statutory compliances and it must be monitored and updated periodically. Compliance Tracker should be maintained in the office of the Hospital Administrator or Medical Superintendent.

The establishment and operations of hospitals in India are governed by a complicated network of statutory requirements aimed at safeguarding the patient safety, ensuring quality, and upholding ethical practices. These regulatory frameworks also depends upon the level and type of the hospital e.g. primary, secondary or tertiary and public or private hospital. In this article we focus mainly on the major regulatory compliances for tertiary care public hospitals, but most of these regulations are applicable to other type and level of hospitals too.

REGULATORY FRAMEWORK

These regulations span diverse domains, such as need of various licenses, biomedical waste management, maintaining radiation safety, comply with labour laws etc. Medical superintendent is considered as person-in-charge/occupier of the hospital. This reflects the multidimensional responsibilities of hospital administration/medical superintendent office. Compliance with statutory regulations is not merely a legal necessity but also important for building trust and ensuring transparency within the healthcare sector. Prominent Acts and rules include the Clinical Establishments (Registration and Regulation) Act, 2010, which mandates the registration of all clinical establishments, the Biomedical Waste Management Rules, 2016, which regulate the safe disposal of hazardous healthcare waste.^(1,2) The Atomic Energy Regulatory Board (AERB) guideline, Labour laws like the Employees' State Insurance Act, 1948, and ethical guidelines issued by the National Medical Commission further contribute to the safeguarding of employee and patient rights.^(3,4)

Article 21 of constitution of India provides the protection of life and personal liberty to the citizens of India making it a fundamental right. India's federal governance structure, as outlined in the Constitution of India, assigns public health, hospitals and dispensaries as a state subject under the Seventh Schedule (List II, State list). This division of responsibilities between central and state governments significantly influences healthcare policy, planning, and implementation, leading to regional variations in regulatory compliance.^(5,6) The regulatory framework governing hospital operations in India comprises a blend of central and state-specific laws designed to standardize healthcare delivery, safeguard patient rights, and ensure institutional accountability on patient and environment care. Some states, including Tamil Nadu and Maharashtra, have implemented their own

clinical establishment laws, leading to regional variations in compliance requirements.⁽⁷⁾ Professional practice standards are governed by the Indian Medical Council Act, 1956, while the Pharmacy Act, 1948, regulates the licensing and operations of pharmacies.^(8,9) We have categorised the statutory requirements into following 2 categories, viz. Operational requirements and the requirements to run specialised services. Table 1 summarises these statutory requirements, their brief description and how to apply for each requirement.

1. Operational Requirements: Operational requirements are critical aspect of hospital management and encompasses adherence to infrastructure standards, safety protocols, and patient rights. Hospitals are required to adhere to fire safety standards as outlined in the National Building Code of India, 2016, and obtain a Fire Safety No Objection Certificate (Fire safety NOC).⁽¹⁰⁾ Accessibility in the hospital for differently-abled individuals is mandatory under the Rights of Persons with Disabilities Act, 2016.⁽¹¹⁾ Patient rights such as informed consent before any procedure, patient privacy, addressing grievances of patients. All these are covered in Charter of Patients' Rights, developed by the National Human Rights Commission.⁽¹²⁾

2. Specialized Services: Hospitals offer various specialized services to the patients,

these specialized services are subject to maintain additional regulations. All these regulations are developed to ensure ethical and safe practices during these services. Such as Organ transplantation in India is regulated by the Transplantation of Human Organs and Tissues Act (THOTA), 1994, where a hospital can only start the service of organ transplant after registering to State health authority under THOTA 1994, which first examines the hospital to look for specific norms for infrastructure, trained personnel, required equipment. Similarly, starting radiological or nuclear medicine services, where there is a risk of radiation harm, safety standards established by the Atomic Energy Regulatory Board (AERB) need to be followed and necessary licenses need to be obtained. Hospitals providing Medical Termination of Pregnancy services must register with the Medical Termination of Pregnancy (MTP) Act, to ensure the safe and ethical delivery of such services.⁽¹⁵⁾

Table 1 summarises Statutory Requirements for Hospitals in India, including relevant regulatory authorities, renewal timelines, descriptions, and brief information on the procedures to obtain individual permissions / licenses. This tabular representation serves as a quick reference guide for hospital administrators / medical superintendents to streamline compliance efforts.

Table 1: Summary of Statutory Requirements for Hospitals in India

Regulatory Requirement	License Issued By	Time Period to Renew	Brief Description	How to Apply
Building Approval	Municipal Corporation/Urban Local Body	One-time approval (unless modified)	Approval for construction or modification of hospital buildings	Submit building plans to the Municipal Corporation/Urban Local Body
Fire Safety NOC	Fire Department	3 years	Certificate to ensure fire safety compliance as per the National Building Code 2016	Submit fire safety audit and other documents to the Fire Department
License for Operating Lifts	Municipal Corporation/Urban Local Body	Every year	Approval for operating lifts in hospital premises	Submit application to the local Municipal Corporation with safety certificates
Electricity Safety Certificate	State Electricity Board	Every 5 years	Certificate ensuring compliance with electricity safety norms	Apply to the State Electricity Board with safety certificates
License for Storing Petroleum/ Diesel	Petroleum and Explosives Safety Organization (PESO)	Every 3 years	License to store petroleum and diesel for generators and hospital vehicles	Submit application to PESO with storage safety measures
Medical Gases and Oxygen Tank Safety Approval	Petroleum & Explosives Safety Organization (PESO)	Every 3 years	Approval for storage and use of medical gases and oxygen tanks	Apply through the Petroleum & Explosives Safety Organization (PESO)

Employees' Provident Fund (EPF) Registration	Employees' Provident Fund Organization (EPFO)	No renewal required, lifetime registration	Registration for compliance with EPF contributions for employees	Register online or offline with EPFO
Permanent Account Number (PAN)	Income Tax Department	No renewal required, lifetime registration	Mandatory tax identification number for hospitals as a legal entity	Apply online through the Income Tax Department's portal
Goods and Services Tax (GST) Registration	Goods and Services Tax (GST) Department	No renewal required, monthly/quarterly filings	Registration for compliance with GST laws	Apply online through the GST Department's portal
Income Tax Filing	Income Tax Department	Annually	Filing of income tax returns for the hospital as an organization	File returns online via the Income Tax Department's portal
Clinical Establishment Registration	State Health Department	1 year (varies by state)	Mandatory registration for hospitals under the Clinical Establishments Act, 2010 or State-specific Act	Submit application with required documents to the State Health Department or online portals
Biomedical Waste Management Rules 2016, Authorization	State Pollution Control Board	1 year	Authorization for segregation, handling, and disposal of biomedical waste	Apply through the State Pollution Control Board's online/offline channels
Registration for Medical diagnostic X-Ray Equipment	AERB	5 years	Registration for the operation of medical diagnostic X-Ray equipment in the hospital. Separate registration for each equipment	Submit application along with details of radiological equipment to eLORA portal of Atomic Energy Regulatory Board (AERB) www.aerb.gov.in/elora
Radiation Safety Approvals for any radiation emitting device	Atomic Energy Regulatory Board (AERB)	Every 5 years	Approval for use of radiological equipment ensuring radiation safety standards	Submit application along with details of radiational device to eLORA portal of Atomic Energy Regulatory Board (AERB) www.aerb.gov.in/elora
Drug License	State Drug Control Department	Every 5 years	License to procure, store, and dispense drugs and pharmaceuticals (Form 20 and 21)	Government hospitals are exempted under rule 123 read with schedule 'K' para 5(A). As the drugs are dispensed and distributed free of cost
Narcotic Drugs and Psychotropic Substances License	State Drug Licensing and Controlling Authority	Every year	License for handling, storing, and dispensing narcotic drugs and psychotropic substances	Submit application to the State Drug Licensing and Controlling Authority
PCPNDT Act, 1994 Compliance	District Health Authority	Every 5 years	Compliance with the Pre-Conception and Pre-Natal Diagnostic Techniques Act for ultrasound services	Apply to the District Health Authority with compliance reports. Form-B (Certificate of registration) is issued to individual Ultrasound machine
Medical Termination of Pregnancy (MTP) Registration	District Health Authority	As per MTP 1971 Act guidelines	Registration for hospitals providing abortion services under the MTP 1971 Act. To provide services of MTP up to 20 weeks of gestation period	Apply to the District Health Authority with required documents for site certification (Form-B)
Blood Bank License	Central Drugs Standard Control Organization	Every 5 years	License to establish and operate a blood bank	Submit application to the State Drug Control Department with compliance reports
Organ Transplant Registration	Directorate General of Health Services (DGHS)	Every 5 years	Registration for performing organ transplants under the Transplantation of Human Organs and Tissues Act	Apply to DGHS with requisite forms and organ transplant committee approvals
Mental Health Establishment License	State Mental Health Authority	Every 3 years	License to establish and operate mental health facilities as per the Mental Healthcare Act	Apply to the State Mental Health Authority with compliance documents

Strategies for Effective Compliance

Maintaining compliance with statutory requirements is mandatory for all hospitals, as non-compliance may lead to legal issues. To cover legal liabilities, mitigate risks, and

to enhance overall operational efficiency, hospitals must adopt strategic approaches. This section outlines key strategies for achieving and sustaining regulatory compliance in healthcare institutions.

1. Role of Hospital Administrators / Medical Superintendents in Ensuring Adherence to Regulations

Hospital administrators' responsibilities encompass the development, implementation, and monitoring of systems designed to align with statutory requirements.

Policy Development	Hospital administrators must formulate and enforce internal policies that are in accordance with regulatory requirements. ⁽⁷⁾ For example, policies on biomedical waste segregation, disposal, maintenance of the records, timely renewal of the certificates. These policies must reflect compliance with respective statutory provisions.
Regular Audits	Periodic internal and external audits are critical to identifying and rectifying compliance gaps ⁽¹⁶⁾ . Administrators can establish a Compliance Tracker, a comprehensive document summarizing all statutory requirements (refer to Table 2) which should be continuously updated and monitored to ensure adherence.
Stakeholder Engagement	Collaboration with regulatory authorities, healthcare professionals, and external auditors ensures a streamlined compliance process and fosters accountability ⁽¹⁷⁾ .
Resource Allocation	Ensuring the availability of adequate financial and human resources dedicated to compliance activities is crucial for sustaining regulatory adherence ⁽¹⁸⁾ .

2. Importance of Training and Capacity Building for Staff

Building the capacity of healthcare staff is fundamental to fostering a compliance-driven culture. Training programs ensure that all employees are well-versed in their regulatory responsibilities.

Awareness Programs	Regular workshops and seminars on key regulations, such as the Clinical Establishments Act, MTP* Act, and Biomedical Waste Management Rules, enhance staff awareness of statutory requirements ⁽¹⁹⁾ .
Skill Development	Specialized trainings equip staff with the skills required to handle sensitive operations, including radiation safety, drug management, infection control and fire mock-drills ⁽²⁰⁾ .
Role-Specific Training	Training programs for various hospital departments facilitate focused learning. For example, pharmacy staff receive training on drug licensing requirements, while maintenance teams are educated on fire safety protocols.

* MTP = Medical Termination of Pregnancy

Table 2: Compliance Tracker

Licences / Certificate / Approvals / Authorizations	Number	Valid from	Valid till	Concerned agency	Remarks
Building Approval				Municipal Corporation/Urban Local Body	
Fire Safety NOC				Fire Department	
License for Operating Lifts				Municipal Corporation/Urban Local Body	
Electricity Safety Certificate				State Electricity Board	
License for Storing Petroleum/Diesel				Petroleum & Explosives Safety Organization (PESO)	
Medical Gases and Oxygen Tank Safety Approval				Petroleum & Explosives Safety Organization (PESO)	
Employees' Provident Fund (EPF) Registration				Employees' Provident Fund Organization (EPFO)	
Permanent Account Number (PAN)				Income Tax Department	
Goods and Services Tax (GST) Registration				Goods and Services Tax (GST) Department	
Income Tax Filing				Income Tax Department	
Clinical Establishment Registration				State Health Department	
Biomedical Waste Management Rules 2016, Authorization				State Pollution Control Board	
Registration for Medical diagnostic X-Ray Equipment				Atomic Energy Regulatory Board (AERB)	

Radiation Safety Approval and
Regulations

Drug License

Narcotic Drugs and Psychotropic
Substances License

PCPNDT Act, 1994 Compliance

Medical Termination of Pregnancy (MTP)
Registration

Blood Bank License

Organ Transplant Registration

Atomic Energy Regulatory Board (AERB)

State Drug Control Department

State Drug Licensing and Controlling Authority

District Health Authority

District Health Authority

Central Drugs Standard Control Organization
Directorate General of Health Services (DGHS)

CONCLUSION

Acts, rules, guideline and licensing requirements setup by the government of India form the backbone of a structured and accountable healthcare system in our country. Adherence to these regulations is a legal obligation for all the healthcare institutes, also to ensure ethical and high-quality healthcare delivery to the citizens. This review article highlights the major statutory requirements that are mandatory for the operations of tertiary care hospitals in India. The critical role of all major statutory regulations is discussed, which includes patient safety, patient privacy, operational efficiency, and institutional credibility. Effective strategies to ensure compliance to these regulations include, fostering a culture of accountability among the hospital staff and prioritizing training and capacity building for the staff. Implementing robust policies, conducting regular audits, and engaging stakeholders. Making a "Compliance Tracker" offers innovative solution for managing regulatory requirements, enabling timely actions and enhancing operational efficiency.

Finally, the journey towards regulatory compliance by the hospitals is not a single time task but a continuous process that demands regular monitoring and interventions. By aligning their practices with statutory mandates, Indian hospitals can not only ensure legal adherence but also build trust, uphold patient rights, and contribute to the broader goal of accessible and equitable healthcare for all.

Conflict of interest: None

Source of funding: None

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