

# Regulation of Private Hospitals in India: Need for a Stronger Legal Framework

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## Abstract:

The private healthcare sector in India has rapidly expanded over the past three decades, delivering essential services in urban and rural areas while attracting substantial investment. Despite the significance and scale of private hospitals, the regulations that oversee them remain fragmented, inadequately enforced and insufficient to safeguard patient rights, ensure quality and control costs. This study examines the existing laws and regulations, identifies deficiencies and inconsistencies and advocates for a more robust and cohesive legal framework. We propose legal modifications that safeguard patients while facilitating growth and innovation within this sector, informed by national policies, judicial rulings and international models. The study concludes by asserting that India's private healthcare sector needs a more robust regulatory framework to ensure equitable access, quality care and accountability for all individuals.

*Keywords:* Private hospitals, healthcare regulation, legal framework, patient rights, quality standards, India.

## I. INTRODUCTION

The healthcare system in India comprises both public and private providers collaborating well. Over the past three decades, the private sector has assumed control of the majority of hospital infrastructure and service provision. Estimates indicate that private facilities deliver around 70–80% of outpatient care and a significant portion of inpatient treatment. Despite their significant role, the government has been unable to match the swift expansion of private hospitals. [1] The government actively manages public healthcare institutions, but private hospitals function under a disparate array of laws, licensing regulations and professional standards that vary significantly across states and regions. [2] The absence of explicit regulations has resulted in several issues, including inconsistent care quality, pricing disputes, unethical conduct and a deficiency of enforceable patient rights.[3] The Indian Supreme Court has emphasized the necessity of legal protections to guarantee standards in private

hospitals, especially regarding negligence and consent. This article evaluates the regulatory state of private hospitals in India, finds legal shortcomings, assesses the implications of insufficient control and underscores the necessity for a complete and integrated legal framework.[4] It concludes with policy recommendations derived on global best practices and the Indian socio-legal framework.[5] From a healthcare systems viewpoint, private hospitals not only furnish treatment infrastructure but also profoundly impact clinical practices, medication utilization patterns, diagnostic decision-making and patient safety standards.[6] Without robust regulatory monitoring, discrepancies in treatment procedures, infection control measures and prescribing practices may arise among facilities. Consequently, a robust legal framework is crucial to guarantee that private healthcare institutions uphold consistent clinical standards, ethical medical practices and secure therapeutic results for patients.[7]

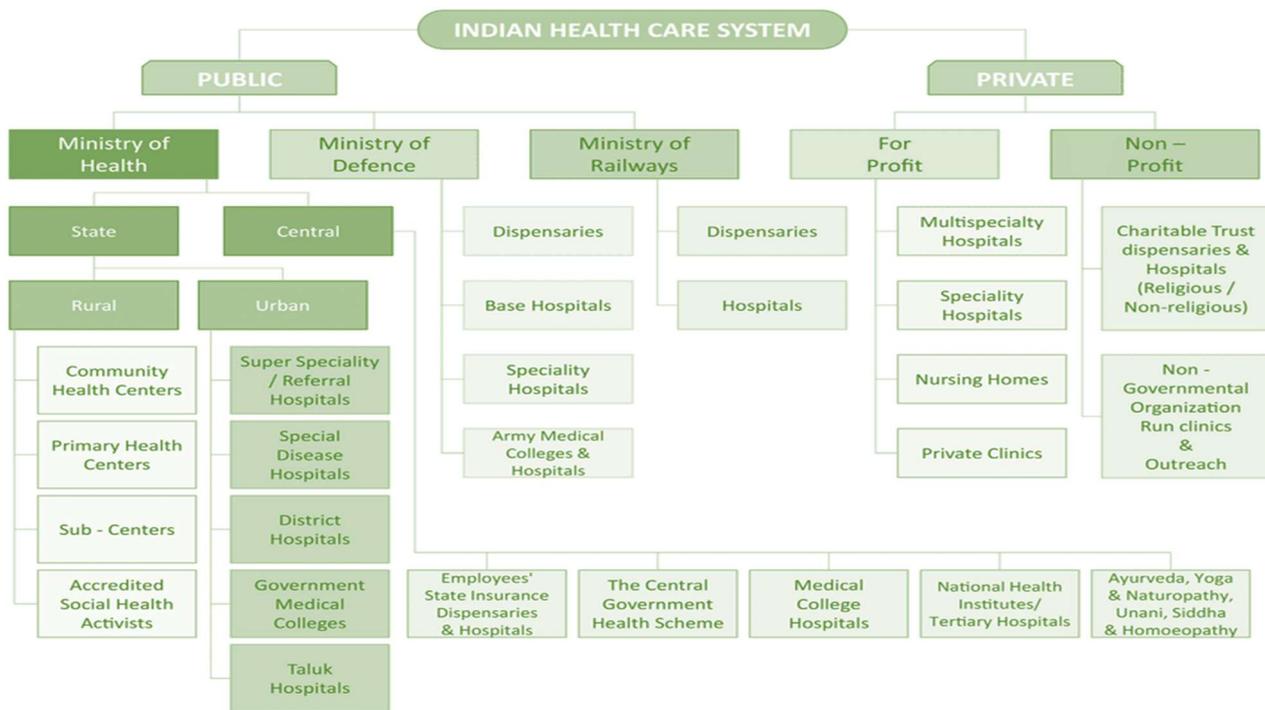


Figure 1: Indian healthcare systems.

**II. BACKGROUND & CONTEXT**

**1. Growth of Private Hospitals in India**

Following the liberalization of the 1990s, India experienced the swift privatization of healthcare services. Investment in medical infrastructure, propelled by increasing demand, medical tourism and entrepreneurial interest, stimulated expansion.[8] The private sector currently includes modest nursing homes, huge corporate hospitals, diagnostic chains and specialist care clinics.

Notwithstanding their significance, private hospitals function within a fragmented regulatory framework. Registration under the Clinical Establishments Act (CEA) is still voluntary for numerous states. Numerous facilities operate without complete adherence to basic standards.[9]

**2. Current Legal & Regulatory Framework**

The Indian Medical Council Act and Professional Codes are two significant statutes governing private hospitals. They establish regulations

governing physician conduct and requisite credentials. [10] The Clinical Establishments (Registration and Regulation) Act, 2010 (CEA) was designed to establish basic requirements; however, only a limited number of states have implemented it.

The Consumer Protection Act of 2019 stipulates that patients may approach consumer forums if they believe they have been aggrieved by a service.

Licensing Regulations of State Health Departments: These regulations vary significantly from state to state, typically emphasizing fire safety, sanitation and fundamental licensing requirements. [11] Medical Negligence Jurisprudence - Legal mechanisms for redress, while reactive and contingent upon individual cases. The various systems exhibit a deficiency in unified enforcement, comprehensive quality and patient safety standards and clear pricing regulation.[12]



Figure 2: Key principles of medical ethics.

### III. LITERATURE REVIEW

#### 1. International Perspectives on Hospital Regulation

Several countries provide models of tight regulation in mixed healthcare systems:

United Kingdom (Care Quality Commission) — Mandates registration and inspection of all hospitals.[13]

Australia (National Safety and Quality Health Service Standards) — Emphasis on continuous quality improvement.[14]

United States (Joint Commission & State Departments of Health) — Accreditation with enforceable conditions, quality metrics and reporting.[15]

Research indicates that statutory regulation and strong enforcement improve patient outcomes, reduce medical errors and enhance accountability. [16]

#### 2. Indian Studies & Critiques

Indian scholars have highlighted critical gaps:

There is substantial inconsistency in regulatory enforcement across states.

Private hospitals often engage in unjustified rate escalation due to lack of price regulation. Patient complaints frequently cite absence of informed consent and discrimination in treatment. Several academics recommend adoption of binding standards, mandatory registration and systematic monitoring.[17]

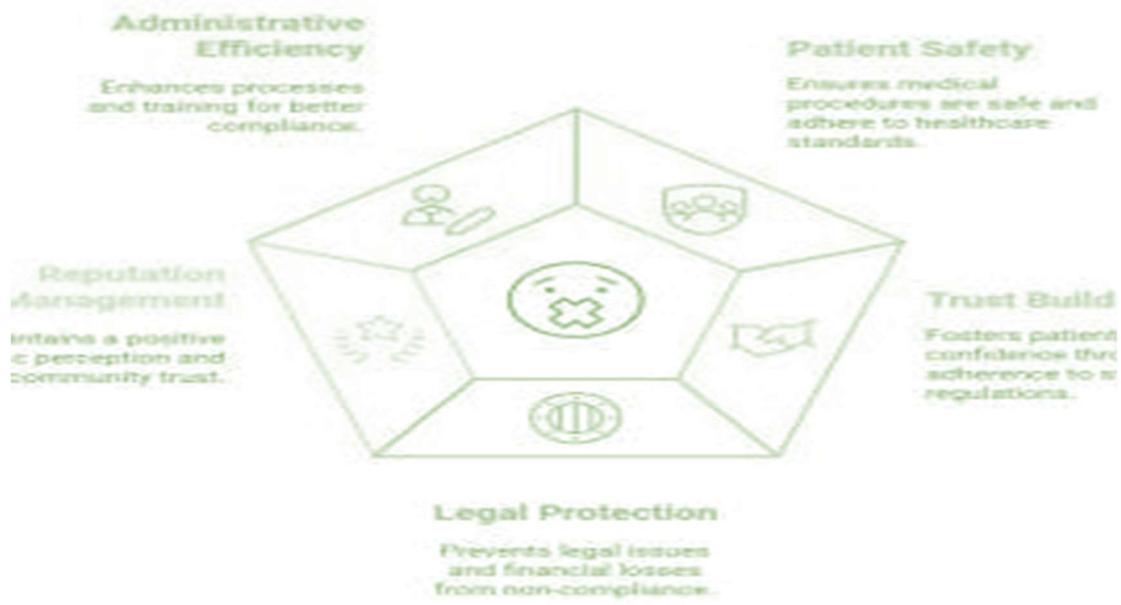
### IV. REGULATORY GAPS AND CHALLENGES

#### 1. Fragmented Legal Framework

Private hospitals are governed by:

Multiple Acts (CEA, Consumer Act, Drugs & Cosmetics Act, Insurance Laws), Diverse state licensing rules, Professional bodies.[18]

This fragmentation leads to confusion, non-compliance and low accountability. Hospitals escape scrutiny by exploiting jurisdictional gaps.



**Figure 3:** Legal compliance in hospital management.

2.

Weak Enforcement

In states that have adopted the CEA, enforcement has been slow and incomplete. Inspections are sporadic, standards not uniformly applied and penalties rarely imposed. Audits and grievance redressal systems are ineffective.[19]

3. Quality Assurance Deficits

Minimum standards (infrastructure, staffing, infection control, record-keeping, clinical protocols) are absent or inadequately enforced. Large hospitals may maintain quality standards for accreditation, but many smaller facilities do not. From a healthcare delivery standpoint, quality assurance at private hospitals is intricately associated with clinical governance procedures, including infection control, rational pharmacotherapy, meticulous maintenance of medical records and compliance with standardized treatment regimens.[20] In numerous smaller private clinics, the lack of structured monitoring systems may result in improper prescribing practices, ineffective antimicrobial stewardship and insufficient reporting of adverse drug reactions. These deficiencies not only jeopardize patient safety but

also undermine the overall efficacy of medical treatment. Consequently, regulatory frameworks must amalgamate legal conformity with clinical quality standards to guarantee safe, ethical and evidence-based healthcare provision in private hospitals.[21]

4. Patient Rights and Consent

Patients frequently face unethical practices: opaque billing, refusal of treatment, unnecessary procedures and lack of informed consent. Current legal recourses (consumer forums or tort law) are slow, reactive and inaccessible for economically vulnerable patients.[22]

5. Pricing & Cost Regulation

Unlike many OECD nations, India has no standardised hospital price list or cap on essential services. This creates unpredictability, catastrophic expenditure risks and systemic inequity. Inflated hospital charges frequently lead to devastating out-of-pocket costs for patients, becoming a primary factor in medical impoverishment in India, hence underscoring the pressing necessity for governmental supervision of private healthcare pricing.[23]



**Figure 4:** Components of quality healthcare.

## V. CASE LAW

### Judicial Commentary on Private Hospital Regulation

The courts have frequently intervened due to inadequate adherence to the laws. Patient Rights: Consent and dignity are emphasized as fundamental rights. Public Interest Litigation: Certain rulings have shown the necessity for improved regulations governing procedural conduct. These rulings indicate that courts are aware of the deficiencies in the law; yet, they are limited to resolving disputes and cannot enact comprehensive legislation. Presented are six significant Supreme Court case laws pertaining to the administration of private hospitals, medical malpractice, patient rights, consent and emergency treatment. India:

#### **1. Parmanand Katara v. Union of India (1989) 4 SCC 286**

**Principle:** Right to Emergency Medical Care

The Supreme Court held that every doctor—whether in a government or private hospital—has a professional obligation to provide immediate medical aid to preserve life. Preservation of human life was declared paramount under Article 21 (Right to Life).[24]

**Significance:**

- Established duty of private hospitals to provide emergency treatment.

- Strengthened constitutional grounding of patient rights.

#### **2. Indian Medical Association v. V.P. Shantha (1995) 6 SCC 651**

**Principle:** Medical Services under Consumer Protection Law

The Court held that medical services fall within the ambit of the Consumer Protection Act, making doctors and private hospitals liable for deficiency in service.

**Significance:**

- Brought private hospitals under consumer jurisdiction.
- Increased accountability for negligence and malpractice.[25]

#### **3. Jacob Mathew v. State of Punjab (2005) 6 SCC 1**

**Principle:** Standard of Care in Medical Negligence

The Court clarified that negligence must be gross or reckless to attract criminal liability. It adopted the Bolam test to determine professional negligence.

**Significance:**

- Defined standard of care for doctors and hospitals.

- Balanced protection of patients with protection against frivolous prosecution.[26]

**4. Samira Kohli v. Dr. Prabha Manchanda (2008) 2 SCC 1**

**Principle:** Informed Consent

The Court ruled that valid consent requires disclosure of nature, risks, alternatives and consequences of treatment. Unauthorized procedures amount to assault and negligence.

**Significance:**

- Strengthened patient autonomy.
- Established legal framework for informed consent in private hospitals.[27]

**5. Paschim Banga Khet Mazdoor Samity v. State of West Bengal (1996) 4 SCC 37**

**Principle:** Right to Health as Part of Article 21

The Court held that failure to provide timely medical treatment violates the Right to Life. Although involving public hospitals, the judgment reinforced the constitutional obligation to ensure accessible healthcare.

**Significance:**

- Recognized healthcare as a fundamental right.
- Influenced regulatory expectations for all healthcare providers.[28]

**6. Kusum Sharma v. Batra Hospital & Medical Research Centre (2010) 3 SCC 480**

**Principle:** Guidelines for Medical Negligence Claims

The Supreme Court laid down principles for determining negligence and emphasized that courts must carefully evaluate expert evidence before holding hospitals liable.

**Significance:**

- Clarified evidentiary standards in medical negligence cases.
- Provided structured guidance for adjudicating claims against private hospitals.[29]

## VI. COMPARATIVE MODELS OF HOSPITAL REGULATION

To identify optimal methodologies, examine the regulations employed by other democracies: The Care Quality Commission (CQC) in the UK oversees obligatory registration, establishes standards, conducts frequent inspections and possesses enforcement authority. [12] The Australian Commission on Safety and Quality in Health Care establishes national standards, mandates ongoing reporting and emphasizes risk management. Japan's Ministry of Health enforces stringent regulations for the classification of facilities and the maintenance of records.

The Ministry of Health in Singapore associates license renewals with quality audits and patient safety protocols. [30] These models share commonalities:

Clearly defined and enforceable standards, routine inspections and assessments, explicit performance indicators and robust mechanisms for lodging complaints. India's socio-economic landscape is distinct; yet, its extensive and varied healthcare system could benefit from the application of analogous concepts.



**Figure 5:** Legal protections for patients with different medical conditions, showing safeguards related to rights, consent, privacy, non-discrimination, and access to care.

**VII. POLICY IMPERATIVES & LEGAL REFORMS**

Nationwide Adoption & Enforcement of the Clinical Establishments Act

The CEA should be made mandatory across all states and union territories, with: Uniform minimum standards, Licensing linked to quality metrics, Periodic audits and public reporting.

Establish a National Hospital Regulatory Authority

A dedicated statutory body with the power to: Set standards for infrastructure, staffing, clinical protocols, Mandate continuous quality improvement, monitor compliance and enforce sanctions, Publish performance indicators. [31]

Standardised Price Regulation

Essential diagnostics, procedures and inpatient care should have:

- Reference pricing guidelines

- Transparency in all estimates presented to patients
- Oversight to prevent exploitative billing

Models from France and Japan that cap procedure prices can guide adaptation while protecting hospitals’ financial viability.[32]

Stronger Patient Rights Framework

A statutory Patients’ Rights Charter is necessary, guaranteeing:

Informed consent, right to a second opinion, Access to medical records, No refusal of emergency care, Grievance and redressal mechanisms with time lines. [11]

Accreditation and Quality Certification

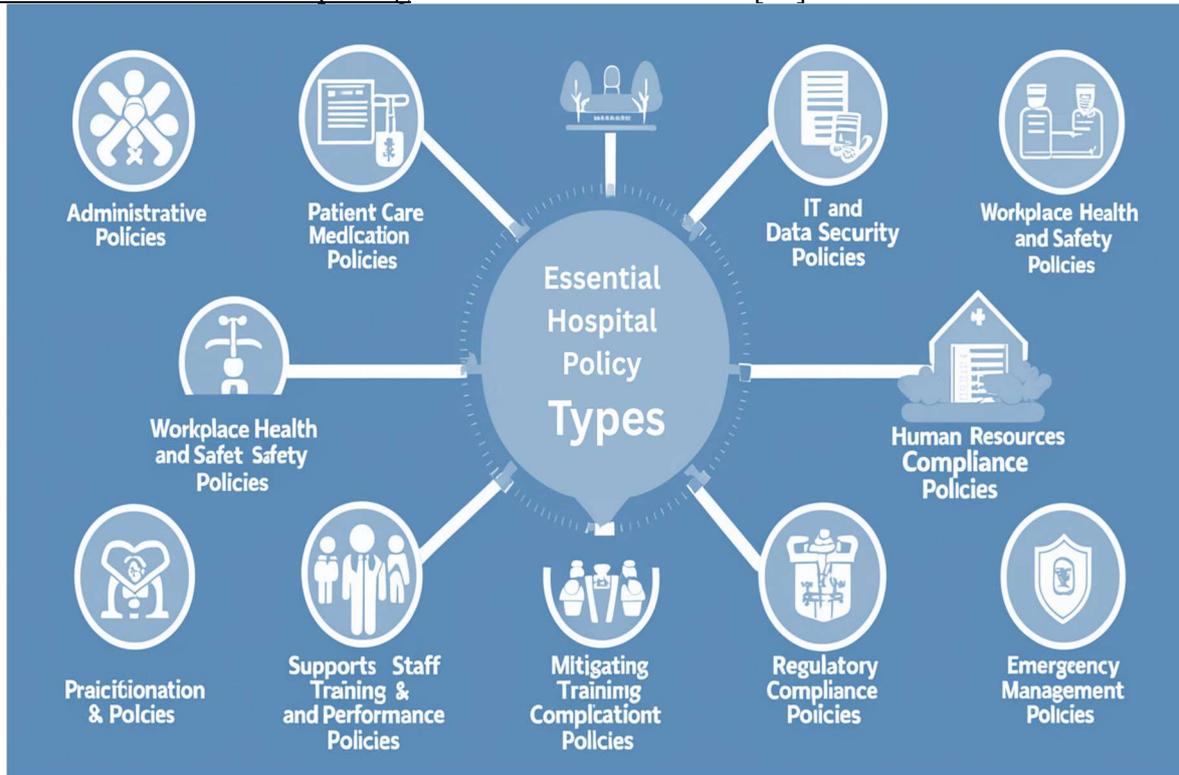
While voluntary accreditation currently exists (e.g., NABH), government support and incentives (or linkage with licensing) should encourage widespread adoption. Accreditation systems foster consistent clinical governance,

enhance patient safety standards and facilitate ongoing quality improvement in healthcare institutions.[30]

Digital Health Records and Reporting

Mandatory electronic health records and:

Data standards, Adverse events reporting systems, Integration with a national health database.[32]



**Figure 6:** Essential hospital policy types, outlining key policies such as patient care, safety, infection control, ethics, and administrative procedures.

**VIII. ADDRESSING IMPLEMENTATION CHALLENGES**

Capacity Constraints

States need trained inspectors, regular audit teams and institutional capacities. Investments in human resources are essential.

Balancing Regulation with Innovation

Regulatory frameworks should avoid overburdening smaller hospitals. Phased implementation and capacity-based standards could help.

Stakeholder Participation

Legal reforms should involve stakeholders: hospitals, clinicians, insurers, patient groups and civil society.



Figure 7: Major healthcare challenges, highlighting issues

**IX. CONCLUSION**

The rapid expansion of private hospitals in India indicates a significant demand for improved legislation and regulations. The existing system is flawed, inadequately enforced and insufficient. It does not provide minimum quality, patient safety, openness, or responsibility. A comprehensive framework is required, grounded in India's constitutional commitment to life and dignity and informed by international models. Key reforms include the implementation of universal standards nationwide, the creation of an independent regulatory authority, robust legislation safeguarding patients' rights, transparent pricing structures and quality assurance mechanisms. These are crucial not only

for safeguarding patients but also for enhancing the reliability and sustainability of India's healthcare system. In the absence of such reform, private healthcare will continue to operate in an opaque manner to regulators, exacerbating inequities and undermining public trust. A robust legal framework will align private interests with the public welfare. This is a crucial advancement in ensuring healthcare is accessible, economical and of superior quality for all individuals. Enhancing regulatory institutions while fostering ethical clinical practices would be crucial for establishing a transparent, responsible and patient-centered healthcare system in India.

Table-1

Section	Key Points
Introduction	Private sector dominates healthcare (70–80% OPD). Regulatory gaps lead to quality, cost, and ethical issues. Need for strong legal framework.
Background & Context	Rapid growth post-1990s liberalization. Fragmented laws like CEA, Consumer Act, state rules with weak enforcement.

<b>Legal Framework</b>	Includes CEA 2010, Consumer Protection Act 2019, Medical Council regulations. Lack of uniform implementation across states.
<b>Literature Review</b>	Global models (UK, USA, Australia) show strong regulation improves quality. Indian studies highlight weak enforcement, high costs, poor consent practices.
<b>Regulatory Gaps</b>	Fragmentation, weak enforcement, lack of quality standards, poor patient rights protection, and absence of price control.
<b>Quality Issues</b>	Inconsistent clinical practices, poor infection control, irrational drug use, lack of monitoring in smaller hospitals.
<b>Patient Rights Issues</b>	Lack of informed consent, transparency, emergency care denial, and weak grievance systems.
<b>Case Laws</b>	Supreme Court emphasized right to emergency care, informed consent, negligence standards, and patient protection under Article 21.
<b>Comparative Models</b>	Countries like UK, Australia, Singapore follow strict licensing, audits, and quality monitoring systems.
<b>Policy Reforms Needed</b>	Mandatory CEA, national regulatory authority, price regulation, patient rights charter, accreditation, digital records.
<b>Implementation Challenges</b>	Lack of trained staff, infrastructure limits, need to balance regulation with innovation, stakeholder involvement required.
<b>Conclusion</b>	Strong unified legal framework needed to ensure quality, affordability, transparency, and accountability in private healthcare.

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