

## Navigating the Legal Landscape of Health Care: Challenges and Evolving Trends in Medical Law

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Cite this paper as: Ramandeep Kaur, Rachit Sharma, Dr. Avishek Raj, Rakhi Tewari, Aastha Thakur, Dr. Anjali Singh, (2025). Navigating the Legal Landscape of Health Care: Challenges and Evolving Trends in Medical Law. *Journal of Neonatal Surgery*, 14 (22s), 158-164.

### ABSTRACT

Globalization poses numerous challenges to the health sector, though it simultaneously opens avenues for growth and innovation. While the health sector holds significant potential, it must navigate the tension between delivering maximum service and operating within limited resources. The overarching goal remains the promotion of human well-being and the protection of fundamental rights. These objectives are achievable largely through the active involvement of state institutions and the implementation of effective legal and policy frameworks. In this context, positive state cooperation and legislative clarity are essential in overcoming systemic barriers and ensuring equitable healthcare access. Furthermore, the proper disposal of medical waste signifies the sector's commitment not only to public health but also to environmental sustainability. In countries like India, where healthcare is both rich in expertise and cost-effective, the sector is evolving into a global hub for medical tourism. However, this progress also brings legal complexities. The evolving landscape of medical law in India demands continual reassessment of regulatory mechanisms, patient rights, ethical considerations, and the responsibilities of healthcare providers. This paper explores the legal challenges in healthcare and highlights the emerging trends in medical law that aim to reconcile justice, efficiency, and inclusivity in a rapidly changing global environment.

**Keyword:** Globalization, Health Law, Medical Ethics, State Cooperation, Healthcare Policy, Environmental Health

### 1. INTRODUCTION

India boasts rather rich medical infrastructure. From the Vedic age to the present, Indian doctors are well-known for their treatment. On all aspects, homeopathy, Ayurveda, Yunani and allopathy on all aspect Indian medical facilities are outstanding. About the health services, there is nothing to compare with other nations. India once more shows itself in the digital age by using the advanced medical facilities to treat all kinds of diseases with a minimum coast. Not only for hospitals but also for medical research India is a fantastic location nowadays. Within few two decades, a new profession trend known as "Medi-tourism" or "medical tourism" emerges in India. India recently saw for the highest numbers of "Medical Visas" issued. Another developing aspect of Indian healthcare is tele-medicine.

Indian medicine is using "Artificial Intelligence" to treat illnesses nowadays. Among the new dimensions in the Indian health care systems produced in recent years are tele health, tele medicines, and robotic-surgeries many more. Along with emphasizing the health sector, the finance minister raises 20% more for drugs and healthcare.

The formulation and implementation of healthcare policies in India are the responsibilities of the central legislative authority, the Ministry of Health and Family Welfare (MoHFW). The paramount authority in India overseeing the quality and delivery of medical services and education is the National Medical Commission (NMC), governed by the National Medical Commission Act, 2019 (NMC Act) and the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. Medical institutions, homeopathy practices, pharmacists, and allied health professions are governed by various regulatory agencies. Each Indian state possesses councils that regulate medical practitioners; legislation enacted in 2023 mandates the replacement of the existing Indian Nursing Council with the National Nursing and Midwifery Commission and the current Dental Council of India with the National Dental Commission. Qualified health professionals must register with the appropriate professional councils to work in India, as each state in India has its own councils to govern medical

practitioners. Each state has enacted legislation that regulates the founding and licensing of hospitals within its jurisdiction. The Indian government has reinvigorated its focus on national healthcare since the onset of COVID-19. The government has budgeted over 900,000 million rupees to the healthcare sector for the financial year 2024–25, aiming to address labour shortages by creating additional medical colleges and intensifying efforts to develop a domestic healthcare industry while reducing dependence on imports. Government funding allocations for healthcare have consistently increased over the years

### **With an eye toward**

The current quality crisis in American healthcare is well known. According to a number of recent studies, "the burden of harm conveyed by the collective impact of all of our health care quality problems is staggering" (Chassin et al., 1998:1005). Plus, as pointed out by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry (1998: 21), "today, in America, there is no guarantee that any individual will receive high-quality care for any particular health problem."

Quite startling are the associated figures. More people die each year as a result of medical errors than from car accidents, breast cancer, or AIDS combined (institute of medicine, 2000). According to Harris Interactive and ARiA Marketing (2000), most Americans are dissatisfied with chronic care. Specifically, 72% of respondents think that patients with chronic diseases have a hard time getting the treatment they need from their doctors. Medical experts are also concerned: According to a 2001 study by Blendon et al., 76% of nurses and 57% of US doctors felt their capacity to deliver quality care had diminished over the past five years due to unsafe working conditions, and 41% said they are discouraged or not encouraged to report medical errors. A third of the 800 doctors polled made a mistake in treating themselves or a loved one (Blendon et al., 2002).

According to the Quality Chasm report's committee, the disparity between the ideal and actual systems was identified by summit speakers, health experts, businesses, health professionals, and students (institute of medicine, 2001). First, there is a lack of attention to detail in the systems and processes that are meant to provide care. Second, the system isn't dynamic enough to adapt to changing patient demographics and related requirements. Third, the science and technology base is growing and getting more complex at a rapid pace. Fourth, the adoption of new information technology to meet patients' demands is slow. Fifth, there isn't enough accommodation for patients' varied demands and needs. Finally, there are staff shortages and bad working conditions.

### **Examining Indian Health Laws: An In- Depth Legal and Judicial Study:**

The Indian Constitution establishes the legal framework for health through its provisions. Article 47 of the Directive Principles of the Constitution of India recognizes the state's primary responsibilities, which include the enhancement of public health, nutrition levels, and living standards. The division is providing technical assistance to the Ministry of Health and Family Welfare in programmatic areas related to legal issues. NHSRC's current intervention areas include the Clinical Establishment Act, Public Health Act, Digital Health Authority Act, Medico-Legal Guidelines and Protocols for survivors/victims of sexual assault, and regulations for human milk banks and lactation management centres.

### **Laws Regarding Healthcare**

The Indian government has enacted various laws to protect individuals' right to health. This pertains to working conditions and industrial hygiene; the prevention and control of occupational, epidemic, and other diseases; and the enhancement of all environmental aspects.

The following are a few of the many purposes that every law serves: -

- MRTP Act for the Indian control abortion program;
- Pharmacy Act deals with the pharma Industries to pharma education & research.
- Maternity law governs welfare for mother and child;
- A law exists to prevent sex determination by means of avoidance.
- Law also penalizes adulterous food.
- Furthermore, covered by consumer laws are health services.

Every company and manufacturing facility is tightly bound to provide their employees with medical amenities.

- Laws also govern the environment aspect of health care.
- Human organs guarded by the laws also
- The laws guard mental health care.
- Not only are human being medications included into the medical system.

Above are the few that list is rather large. Every institution in India, including Parliament to Courts, is helping to safeguard Indian human being.

#### **Judiciary in charge of health care**

- All of the Indian health system covers physical health as well as mental health. Every institution of Indian government is accountable for properly tending to the humanity by carrying out their roles.
- The watchdog defending Indian citizens' health rights in India is their own Constitution. Different precedents are establishing that the Indian Constitution's "right to life" comprises the "right to health".
- Arts: The Indian Constitution covers the fundamental rights 14, 15, 16, 20, 21, 23 and 24. Arts are Directive Principles of State policies contain 38,39, 40, 41,42, 47,48-A to impose obligations on the state to prepare a rigorous framework for every Indian citizen.
- Under Art. 51-A (g), we are duty bound to have compassion for living entities and to protect and enhance the natural surroundings including forests, lakes, rivers, and wild life.

Through safeguarding of human rights, Indian Judiciary also established several values to preserve the humanity. The Indian Judiciary shields some rights mentioned below from infringement; -

- Every individual possesses an inherent right to existence. One ought to exist with a sense of human dignity.
- The Obligation of Medical Assistance: It is incumbent upon states to ensure that their citizens, who are unable to access existing medical facilities, receive the necessary medical aid.
- The well-being of individuals: It is the duty of states to provide their citizens with complimentary medical services, thereby enhancing their overall welfare. The Indian Constitution mandates the state to enhance medical facilities, thereby promoting public health.
- Essential Elements of a Significant Right to Life: Within the framework of consumer law, medical facilities are included, and it is their obligation to safeguard the health of others as well.
- The safeguarding of life is encompassed within the right to life as articulated in the Indian Constitution; consequently, human health is inherently included.
- The environment is intrinsically linked to health; the Constitution of India guarantees the right to a healthy environment alongside health legislation.
- A sound body and mind: Each human endeavor plays a role in fostering optimal mental and physical well-being.
- The Supreme Court observes in Parmanand that every individual who experiences an accident possesses the right to prompt medical treatment.
- The right to health is both a fundamental and a human right, as evidenced by various international instruments.
- Similar to multi-functional hospitals found in urban centers, primary health care facilities represent an inherent entitlement of the populace. The state not only protects the health of its citizens but also upholds the well-being of its workforce in accordance with its obligations.

#### **Patient Rights and the Doctor-Patient Interaction**

Emphasized through recent legal changes, one of the basic components of the medical-legal framework in India is the defence of patient rights. The Supreme Court underlined in the historic ruling in *Samira Kohli v. Dr. Prabha Manchanda* (2008) that patients must be fully informed of the hazards, alternatives, and possible results of any treatment. For doctors, this calls for open communication and meticulous documentation to guarantee correct informed consent.

The Consumer Protection Act, of 2019, which replaced the 1986 Act, marks still another important change. The new law

calls for tougher fines and extends consumer rights. Crucially for doctors, healthcare services are now clearly covered under the Act, so allowing patients to report medical negligence before Consumer Commissions. This change emphasizes the need of keeping appropriate medical records, following ethical guidelines, and guaranteeing open communication with patients.

### **Medical Negligence and Malpractice:**

For medical professionals, one of the most delicate legal concerns still is medical negligence. Negligence in healthcare is the result of a provider violating their duty of care to the patient and so causing damage or injury. The "Bolam Test" for negligence established by the 2005 Jacob Mathew v. State of Punjab ruling compares doctor behaviour to that of a reasonably competent peer in the same field. Crucially, negligence cannot be criminal without involving "gross negligence," or reckless behaviour.

**Dr. Suresh Gupta v. Government.** This position was strengthened by the 2004 NCT of Delhi case, which underlined that criminal prosecution for medical negligence should be restricted to situations whereby there is a clear and gross departure from the accepted standard of care. This emphasizes, to doctors, the need of following accepted medical guidelines and keeping thorough patient records.

### **Act on Clinical Establishments (Registration and Regulation) 2010**

Doctors who run or oversee medical facilities depend critically on the Clinical Establishments (Registration and Regulation) Act, 2010. This Act requires that all clinical facilities—including hospitals and private clinics—follow recommended guidelines of care, infrastructure, and personnel and be registered. Regular inspections and audits help to guarantee compliance; non-compliance may result in fines, including the suspension of the establishment's registration.

Ensuring that their practice conforms with the Clinical Establishments Act helps doctors stay free from legal challenges. These covers satisfying the guidelines for facility management, documentation, and patient care.

### **New Regulator: National Medical Commission**

The National Medical Commission (NMC) took over from the Medical Council of India (MCI) in 2020 as the regulatory body supervising medical practice and education in India. Improving access to quality healthcare, controlling medical education, and guaranteeing that doctors follow professional standards fall to the NMC.

Ethical practices—including the value of informed consent, patient confidentiality, and the ban of needless treatments—have been one of the main areas of emphasis the NMC has addressed. Under the NMC rules, doctors are expected to maintain the best ethical standards and suffer harsher fines for infractions.

### **Digital health and telemedicine: negotiating legal obstacles**

Particularly since the COVID-19 epidemic started, telemedicine has expanded rather dramatically in India. Published by the National Medical Commission, the Telemedicine Practice Guidelines, 2020 offer a legal foundation for teleconsultations. Under the Information Technology (IT) Act, of 2000 doctors have to make sure telemedicine consultations are appropriately recorded, consent is obtained electronically, and patient data privacy is kept. Healthcare professionals entering telemedicine must keep current on policies to avoid possible legal hot spots, particularly with relation to patient consent and data privacy.

### **The Indian Healthcare Industry's Scene**

India's healthcare sector is a complex ecosystem that includes both public and private healthcare institutions, along with pharmaceutical and medical device companies. The healthcare industry in India is governed by a comprehensive framework of regulations and laws at various stages, as established by the authorities and regulators. It is essential for healthcare companies to adhere to the applicable laws to ensure robust compliance concerning their interactions with healthcare professionals and patients. Ethical lapses and non-compliance exacerbate these challenges and may lead to a decline in the quality of healthcare services, as well as disparities in access to treatment. **The following justifies the great relevance of ethics and compliance in the healthcare sector:**

- Patients depend on medical experts to make decisions in their best interests; hence, ethical behaviour forms the basis of this confidence. Patients are more likely to feel safe and confident in their treatment when institutions and medical professionals follow moral values.
- Medical ethics and compliance depend mostly on keeping trust and openness in a doctor-patient relationship; hence, responsibility and openness inside the healthcare sector are fostered by them.
- Following accepted rules and guidelines helps healthcare companies and professionals to keep accurate records, document negative events, and own their actions. Transparency like this helps patients and stakeholders to develop confidence.

In healthcare, ethical behaviour directly affects the calibre of patient treatment. Those in the healthcare field that give ethics top priority are more likely to provide excellent, patient-centred treatment. This covers informed permission, honouring patient autonomy, and rendering treatments consistent with the values and choices of the patient. Ethical behaviour guarantees that other ulterior motives or financial gain does not compromise patient care. In the healthcare sector, ethics and compliance are intimately entwined and typically follow legal and regulatory guidelines. Maintaining the integrity of the healthcare system depends on one following these guidelines.

### **The Indian Situation**

The Indian government has incorporated this into many statutory laws and regulations to ensure that healthcare personnel adhere to their legal obligations and compliance, recognizing that ethics and compliance are fundamental to success and safety.

On August 3, 2023, the National Medical Commission (NMC) issued the National Medical Commission Registered Practitioner (Professional Conduct) Regulations, 2023 (RMP Regulations), which became effective on August 9, 2023. Subsequently, the National Medical Commission published the Registered Medical Practitioners (Professional Conduct) (Amendment) Regulations, 2023 ("Amendment") on August 23, 2023, therefore placing the RMP Regulations in abeyance with immediate effect. The NMC has emphasized that the RMP Regulations would not be operational or effective until further notice is published in the official gazette. Moreover, it is crucial to emphasize that the Amendment has reinstated the previously superseded Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 ("IMC Regulations"), rendering them active once again. The RMP Regulations were intended to mandate that RMPs publicly disclose their relationships with pharmaceutical corporations and associated health sector industries in a clear, transparent, and examinable manner. The RMP Regulations are presumed to be unfriendly to the sector, suggesting that a modification is probable.

The IMC Regulations are essential laws and standards that govern the ethical conduct of registered medical practitioners (RMP) in India. The Indian Medical Council, the authority responsible for regulating medical practice and education in the country, established these regulations. The primary objective of the IMC Regulations is to establish and maintain rigorous ethical standards within India's medical sector. Highlighting the importance of patient welfare and professional integrity, it delineates the principles and regulations that Registered Medical Practitioners must adhere to in their practice. These regulations explicitly delineate the responsibilities of the RMPs, which encompass upholding exemplary medical practice, preserving medical records in the prescribed manner, utilizing generic drug nomenclature, ensuring the highest standard of patient care, and disclosing unethical conduct, among others.

Multiple instances have highlighted the ethical misconduct and non-compliance of Registered Medical Practitioners (RMPs); a prominent example is the widely reported case of Apex Laboratories v. Deputy Commissioner of Income Tax, Large Tax Payer Unit-II, wherein a pharmaceutical company was required to justify expenditures related to gifts such as hospitality, conference fees, gold coins, LCD televisions, refrigerators, and laptops provided to medical practitioners. The Supreme Court determined that the firm breached the IMC Regulations and that the medical practitioner clearly committed an offense by taking gifts from the company, as such actions are explicitly prohibited by law. The court observed that "the freebies are not genuinely 'free' – the expense of providing such items is typically incorporated into the drug's price, thereby establishing a continuous cycle of public detriment." These factors are propelling prices.

Several significant regulations govern the healthcare sector, including but not limited to the Uniform Code on Pharmaceuticals Marketing Practices and the Draft Uniform Code on Medical Device Marketing Practices issued by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers.

The Prevention of Corruption Act, 1988 ("POCA") is significantly pertinent as it regulates the acceptance of gratification by a public servant concerning an official act, except lawful remuneration, or by corrupt legal methods or criminal wrongdoing by a public servant. Enacted in 2018, the Prevention of Corruption (Amendment) Act, 2018 encompasses commercial entities—specifically, businesses registered or operating in India—and their employees involved in offering any undue advantage to public officials to: secure or retain business for the commercial entity; or obtain or maintain a benefit in the operation of the commercial entity. Under the POCA, the individual (an officer or employee of the commercial organization) who provides an unfair advantage, along with the organization itself, will be held liable unless the organization can demonstrate that it had adequate policies to prevent such conduct by associated individuals.

In addition to the previously mentioned points, the IPC serves as India's criminal code, encompassing all essential aspects of criminal law, such as abetment, criminal misappropriation, criminal breach of trust, and cheating, thereby impacting stakeholders within the healthcare ecosystem, including medical practitioners who partake in such activities.

### **General Foreign Legislation Regarding Bribery and Corrupt Practices**

The top 20 industries receiving foreign direct investment (FDI) equity inflows from April 2000 to June 2023 include the



healthcare industry, encompassing medications, pharmaceuticals, and hospital and diagnostic centre sectors. The United States, with a 9% stake, and the United Kingdom, with 5%, rank among the top 10 nations for foreign direct investment equity inflows into India for the financial year 2022–2023. India imports over 80% of its medical products from foreign corporations, operating via a network of distributors and agents or through subsidiaries. It is crucial to consider the peculiarities of the regulations of different nations regarding ethics and compliance in the healthcare sector, as these often impact subsidiaries and/or distributors in India. Under the Foreign Corrupt Practices Act of 1977 (“USFCPA”), the Department of Justice and the Securities and Exchange Commission investigate and penalize corporate wrongdoing in the United States. The USFCPA prohibits the bribery of foreign government officials and mandates accounting and internal control requirements for US-based enterprises. The UK Bribery Act, 2010 (“UKBA”) applies to all enterprises, or segments thereof, operating within the UK, as well as those established under UK legislation, and is enforced by the UK Serious Fraud Office. The UKBA prohibits both the bribery of foreign public officials and the acceptance of bribes; the inability of business enterprises to prevent bribery is a further concern. The USFCPA and UKBA’s general and extraterritorial sections empower authorities in the US and UK to scrutinize corporations within their jurisdictions, together with their subsidiaries, distributors, and agents, to ensure compliance with relevant laws. Recent harsh fines and penalties for breaches of pertinent anti-bribery regulations have been imposed on multiple US and UK corporations. The structure of the healthcare sector in India is significantly influenced by ethics and compliance. Legal compliance, patient confidence, and treatment quality are assessments to detect trends and patterns of violations; (b) ongoing training and education for employees regarding procurement practices, vendor selection, conflicts of interest, and the encouragement of reporting suspicious activities; and (c) comprehensive oversight and regulation of the procurement cycle and employee conduct. These concepts are essential for delivering equitable, accessible, and high-quality healthcare services to all individuals within a diverse and extensive healthcare landscape. The importance of ethics and compliance must not be overlooked as the Indian healthcare system evolves. In addition to a moral obligation, pursuing ethical excellence and regulatory adherence is strategically essential for the sustained growth of the Indian healthcare sector.

## 2. CONCLUSION AND WITH RECOMMENDATIONS

Healthcare is an essential necessity that must be preserved; it is also ensured and remedied by the government and is a fundamental right in India. Currently, medical facilities are beginning to exhibit indications of corruption. Healthcare personnel referred to as medical terrorists and hospitals transformed into facilities of mortality. The state is responsible for all these matters, and each of us shares equal culpability for this situation.

The intricate and always evolving medical-legal framework of India Doctors must remain updated on the latest legislation changes, including the Consumer Protection Act of 2019, the Clinical Establishments Act of 2010, and the National Medical Commission regulations. Adhering to these regulations enhances the quality of patient care and protects medical professionals from legal liabilities.

Comprehending legal requirements and adhering to ethical norms enables physicians to mitigate the risk of legal disputes and focus on delivering optimal healthcare standards. All healthcare practitioners in India must remain informed and proactive due to the continual evolution of regulations and norms.

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