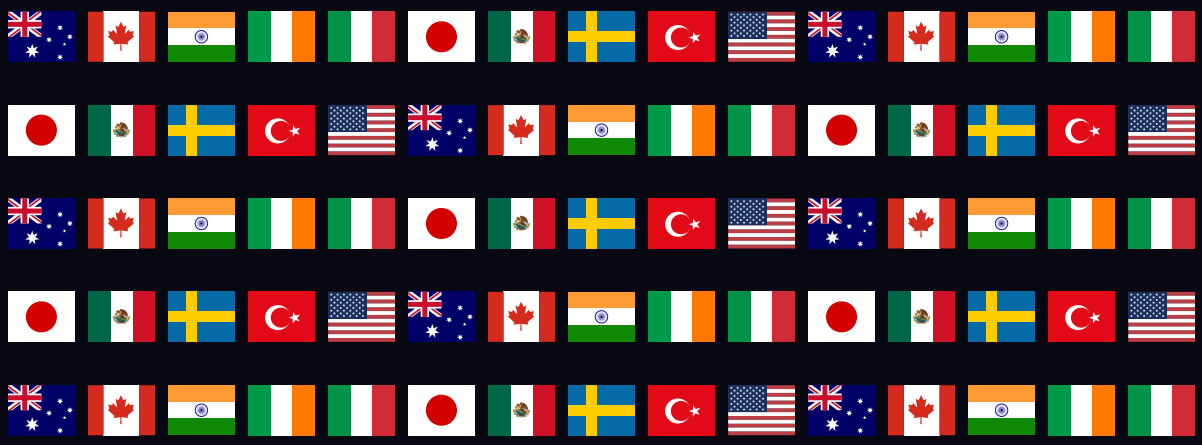
HEALTHCARE REGULATION

India



LEXOLOGY
Getting The Deal Through

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Norton Rose Fulbright

Healthcare Regulation

Consulting editors

Susan Feigin Harris, Kathleen Rubinstein, David Aplington, Elise LeGros, Jeff Wurzburg

Norton Rose Fulbright

Quick reference guide enabling side-by-side comparison of local insights, including into organisation, financing and structure of the healthcare system; pricing and reimbursement; healthcare organisations and business structures; competition, anti-corruption and transparency; regulation of healthcare services and professionals; data protection, privacy and digital health; and key developments.

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UPDATE AND TRENDS

Contributors

India

Manisha Singh
manisha@lexorbis.com
LexOrbis

Pankaj Musyuni
pankaj@lexorbis.com
LexOrbis

ORGANISATION, FINANCING AND STRUCTURE OF THE HEALTHCARE SYSTEM

Organisation

How is healthcare in your jurisdiction organised? What is the role of government?

There are both public and private hospitals and clinics in India. In India, private hospitals provide the vast majority of tertiary care. The healthcare system consists of primary, secondary and tertiary levels of treatment. The majority of community-based public health programmes provide primary care services with the aim of reducing communicable and noncommunicable disease-related mortality and morbidity. Both primary and secondary care facilities offer standard medical care. Most district capitals offer tertiary care through community clinics, district hospitals and medical colleges. Primary healthcare facilities serve as the primary medical centres for populations of 20,000 or more in tribal areas. The Basic Minimum Services Programme and the Minimum Needs Programme are used to construct and maintain government-run hospitals. Practitioners in primary healthcare treat and prevent illness. Community health centres are supported by both the Medicare Nonprofit Partnership and the Medicaid Managed Care System. Rural areas with populations of 120,000 or more, as well as hilly and tribal regions with populations of 80,000 or more, must establish a state-run community health centre (CHC). CHCs are required to employ physicians, surgeons, obstetricians and paediatricians. Each CHC in the nation is equipped with 30 beds, an operating chamber, X-ray capabilities, a work area and a laboratory. Obstetric care and counselling are offered at primary care facilities in the vicinity.

The government of India is heavily concerned with healthcare. In India, the Ministry of Health and Family Welfare is responsible for public health. The government operates a variety of medical facilities, including those for the general public, the military and the poor. The government offers both health insurance and financial aid for medical care. The government of India finances healthcare programmes that enhance both accessibility and quality. The government of India guarantees that its citizens have access to high-quality medical care. The NRHM offers primary care, services for mothers and children, and pandemic preparedness to rural Indians. Additionally, the NRHM provides funding for rural Indian hospitals and clinics.

The Indian government supports global healthcare initiatives. The India Global Health Initiative finances healthcare activities that seek to improve public health outside India. These measures decreased disease transmission and enhanced community health. The Indian government facilitates access to high-quality medical care for its citizens.

Law stated - 28 July 2023

Key legislation

What key legislation governs the provision of healthcare services in your jurisdiction?

The Indian Medical Council Act 1956 and Regulations 2002; the Indian Nursing Council Act 1947; the Dentists Act 1948; the Pharmacy Act 1948; the Rehabilitation Council of India Act 1992; the Indian Medicine Central Council Act 1970; the Homeopathy Central Council Act 1973; and the Clinical Establishments Act 2010 are all concerned with the quality of health personnel education and training.

Law stated - 28 July 2023

Financing

How is the healthcare system financed in the various patient care sectors?

The Indian government guarantees the ‘right to health’, as stated in the Constitution. All state residents, regardless of their socioeconomic situation, should have access to high-quality medical care. In contrast, India’s healthcare budget

has consistently fallen short of requirements. Most materials used in public buildings in India are funded by the federal government. In India, government-funded health insurance schemes do not cover outpatient care. In India, private health insurance only covers hospitalisation. All Indian citizens have access to inpatient and outpatient care at government facilities. Due to the decentralised nature of India, local states are responsible for providing healthcare. Due to a dearth of services, numerous individuals are forced to seek out and pay for private counseling. In India, neither public nor private health insurance covers ambulatory care; all costs must be covered by for-profit providers. Due to the Pradhan Mantri Ayushman Bharat and the Jan Arogya Yojana programme, those with lower incomes can now receive secondary and tertiary care at private facilities for free. The availability of health insurance alternatives varies between public and private sector employees. The private voluntary insurance market is under-utilised despite its existence. In 2018, the government launched the National Health Protection Scheme to provide health insurance to low-income citizens. Private hospitals and clinics can provide free tertiary and secondary care under this system.

Law stated - 28 July 2023

Delivery structures

What are the basic structures for the delivery of care to patients in your jurisdiction?

The Indian healthcare system includes both public and private services. However, the majority of private secondary and tertiary care providers in India are concentrated in the nation's main cities. Individuals in India have access to both non-profit and for-profit healthcare facilities. Private hospitals are only located in major metropolitan areas, whereas public hospitals are nearly ubiquitous. There is a public hospital in every major city. Many low-income households find private hospitals to be prohibitively expensive. On the other hand, a public hospital is more accessible. The distinction between public and private hospitals is based on whose ownership or control they are under. The wait periods at private hospitals are significantly shorter than those at public hospitals. Public hospitals, unlike private hospitals, serve numerous patients simultaneously. Despite the fact that many Indians use private healthcare, only a small portion of them have such policies. Because India lacks a regulatory body, private healthcare services and insurance may be prohibitively expensive. Unfortunately, many individuals incur substantial debt while pursuing medical care.

The calibre of medical care can vary significantly from one location to another. The services and amenities available to affluent foreigners and local expats are vastly different from those available to common locals. Public hospitals are those that receive full or partial government funding; they are adaptable and take the majority of health insurance plans. Patients are aware that private hospitals charge a premium for their services because they may offer a marginally more comfortable environment than large public hospitals. Regardless of whether your insurance covers it or not, these clinics frequently charge a premium for the same medical care.

In addition, the condition of these private facilities is significantly superior to that of their government counterparts. Waiting times are reduced, and the team is composed of a wide range of professionals. The accommodations are spacious and well appointed; the food is exquisite; and the service is impeccable. In contrast, the Indian rural healthcare system is, at best, fragile. The vast majority of Indian physicians (74 per cent) operate in urban areas. The rural areas of India are vast, but physicians are scarce. Particularly dissatisfied with the dearth of affordable housing, educational options and infrastructure are rural educators and medical professionals. There are also a number of hospitals and other medical facilities. The number of beds in rural facilities is half that of urban facilities. However, small-town hospitals typically lack cutting-edge medical equipment. This will have catastrophic effects on the region's healthcare. For instance, the infant mortality rate is higher in rural areas than in urban areas.

Law stated - 28 July 2023

Access and coverage

What rules govern access to treatment and emergency services? Which items and services are covered and which are not covered?

Prompt and quality healthcare in an emergency can mean the difference between life and death. Article 21 of the Indian Constitution of 1950 protects everyone's right to life, which includes the right to emergency medical care. Furthermore, all medical professionals and doctors in both private and government hospitals have a responsibility and duty to the community's health.

Law stated - 28 July 2023

Exclusions from statutory coverage

Are any groups excluded from statutory coverage? Are any groups covered under alternative schemes?

No, the emergency services are not categorised and are open to all.

Law stated - 28 July 2023

Gaps in cost coverage

Are there any gaps in cost coverage?

Yes, it depends on the services and costs included in providing the medical services.

Law stated - 28 July 2023

HEALTHCARE PRICING AND REIMBURSEMENT

Pricing

How are prices for healthcare services set and paid for in your jurisdiction? To what extent is the cost of healthcare services governed by law or regulation?

The Drugs (Prices Control) Order of 1995 (DPCO) regulates and supervises the prices of pharmaceutical goods. The National Pharmaceutical Pricing Authority (NPPA) was established on 29 August 1997, as an independent group of experts charged with addressing a variety of issues, such as updating the list of medications subject to price controls based on established criteria and guidelines and locating and storing data on production, export, import and corporate profitability for bulk medications or formulations.

The DPCO of the Department of Pharmaceuticals, which was published on 15 May 2013, considerably increased the number of drugs subject to price caps and altered price regulations. In 1995, the former DPCO was only in charge of 74 bulk medications, whereas the current DPCO is responsible for 348 pharmaceuticals. In 2013, Rule 123E of the Food, Drug, and Cosmetic Act created a new category of patentable pharmaceuticals. In contrast, the NPPA will act if the annual increase in retail prices for non-scheduled pharmaceuticals (over which it has no control) exceeds 10 per cent. Because they are not subject to direct price limitations, manufacturers of non-scheduled products are not required to conform to NPPA pricing approvals. In addition, it is prohibited for the government to charge higher prices for non-scheduled bulk pharmaceuticals than the public considers reasonable in terms of fixed or adjusted pricing.

Law stated - 28 July 2023

Reimbursement

How is reimbursement for healthcare services structured?

Through a variety of insurance programmes, including the Employees State Insurance Scheme (since 1952) and the Central Government Health Scheme (since 1954), the government has attempted to provide financial assistance for healthcare. Despite their prevalence among Indian citizens, these programmes only allowed selected recipients to obtain health insurance at the state or national level and were incapable of attaining universal health coverage on their own. People ineligible for these programmes continued to incur out-of-pocket medical costs. The Indian national health system covers patients enrolled in the Central Government Health Scheme or the Employees' State Insurance Scheme. Private insurers must cover a minimum of 24 hours in the hospital, per the provisions specified in their portfolios. In addition, the patient is reimbursed for up to 30 days prior to admittance and 60 days following discharge. Private insurers do not cover the cost of medications used to treat chronic conditions such as hypertension, diabetes and other long-term conditions.

Law stated - 28 July 2023

Adjudication

If applicable, what is the competent body for decisions regarding the pricing and reimbursement of healthcare services?

The NPPA was established on 29 August 1997, as an independent organisation of experts charged with determining the pricing and reimbursement of medical products. In India, there is no universal funding or reimbursement system for pharmaceuticals. Notwithstanding, several federal and state programmes provide free or subsidised pharmaceuticals and financial assistance for medical procedures, predominantly for those living below the federal poverty line and in rural areas.

Law stated - 28 July 2023

HEALTHCARE ORGANISATIONS AND BUSINESS STRUCTURES

Legal authorisation

What steps are necessary to authorise the provision of healthcare services, and what laws govern this?

In India, there are two types of hospitals: public and private. General, specialty and multi-specialty hospitals exist. The Clinical Establishment Act of 2010 was enacted by the central government to facilitate the establishment of private hospitals in India. Only one registration is required. The Act requires the registration of all clinical facilities, including diagnostic centres and single-doctor clinics, in the public and private sectors, with the exception of those administered by the military, in all recognised medical systems. The registering authority facilitates policy formulation, resource allocation and the establishment of treatment standards. It has the authority to impose sanctions on those who violate the Act's provisions. In accordance with the Act, a core council of specialists has developed Standard Treatment Guidelines for common medical conditions. This law requires all clinical facilities to provide the necessary medical treatment and care to stabilise all patients who enter or are transported to the facility in an emergency medical condition, including women and accident victims. In contrast, section 12 of the Act stipulates that for a clinical establishment to be registered and maintained, it must meet certain conditions, including:

- facilities and service standards that meet or exceed the absolute minimum;
- personnel requirements that exceed the bare minimum; and
- recordkeeping and maintenance provisions.

The minimum standards for hospitals depend on the calibre of care they provide. Each state government has utilised this law to expedite the hospital registration process. In addition to firm registration, a memorandum of association, articles of incorporation and capital structure are necessary. Also required is the verification of financial assets and account information. Each director is assigned a Director Identification Number by the Minister of Corporate Affairs. Legally, managers who desire to work for a company must register with the government prior to employment (registration is required only once). In addition, registration is required by the 2013 Companies Act .

Law stated - 28 July 2023

Legal structures

What types of legal entities can offer healthcare services?

In India, any approved hospital can offer medical services to the general public. Regional and/or zonal health and family welfare departments with more divisions than their national counterparts must implement laws governing healthcare delivery. According to the National Council for Clinical Establishments, all requirements must be met under the Clinical Establishments Act of 2010. The National Medical Commission is responsible for regulating medical education and practice, while the Central Drug Standard Control Organization is responsible for enforcing the Drugs and Cosmetics Act. Both organisations receive funding from the Department of Health and Family Services. Moreover, based on the circumstances of the case, Indian courts have the authority to impose healthcare regulations and laws.

The Ministry of Health oversees the healthcare infrastructure in India. The General Directorate of Health Services accumulates and archives medical and health-related research for policy and practice applications. The Central Drug Standard Control Organization has established stringent guidelines for the distribution of pharmaceuticals, cosmetics, diagnostics and medical equipment in the United States. The importation and licensing of pharmaceuticals, the certification of new pharmaceutical products for sale and the need for clinical trials are all subject to oversight. The National Pharmaceutical Pricing Authority routinely revises the list of medications subject to price restrictions based on export and import criteria and pharmaceutical company market shares.

The National Medical Commission regulates the medical field and ensures that all individuals have access to high-quality healthcare. The Drug Controller is India's primary pharmaceutical regulator, responsible for a variety of tasks including drug licensing and control, clinical study supervision, the introduction of new products and the issuance of import licences. Obtaining a licence from the Food Safety and Standards Authority of India is a prerequisite for any entrepreneur interested in the Indian food market. All sales of nutritional supplements, organic foods, functional foods and nutraceuticals require these authorisations in India.

Among the ministries and government institutions responsible for Indian healthcare are the Ministry of Health and Family Welfare, the Ministry of Ayurveda, the Ministry of Ayush, the Central Drugs Standard Control Organization, Unani, Siddha and Homoeopathy.

Law stated - 28 July 2023

Foreign companies

What further steps are necessary for foreign companies to offer healthcare services?

All new companies must register under the Companies Act of India (2013), whether they are domestic or foreign. This law simplifies international commerce for India. A foreign company that wishes to conduct business in India may either organise a joint venture with an Indian company or establish a wholly owned subsidiary. Multinational corporations can access the Indian market through joint ventures or wholly owned subsidiaries in sectors where 100 per cent foreign direct investment (FDI) is permitted. In the nuclear power, lotteries, gambling and real estate industries, FDI is prohibited.

The 2013 Companies Act governs business formation, administration, reorganisation and dissolution. The 2002 Competition Act regulates merger regulations and anticompetitive conduct. In light of India's expanding economy, the Act established a commission charged with preventing anticompetitive practices, promoting and sustaining market competition, safeguarding consumer interests and ensuring other market participants' freedom of trade. In addition, it addressed matters that were tangential to or relevant to these objectives. The I ncome Tax Act equally to corporations and partnerships when it comes to dividends and capital gains. Its primary goal is to improve the lives of all Americans through the simplification of the tax code. The Indian Contract Act sets out the overarching principles that govern the creation and execution of contracts in order to ensure that the rights and obligations arising from a contract are met and that those adversely affected by a contract have access to legal remedies.

In addition to sectoral restrictions, the Foreign Exchange Management Act (FEMA) of 1999 regulates currency and investment flows into India. The primary purpose of the FEMA law was to facilitate the orderly growth and preservation of India's foreign currency market and to make it easier for Indian companies to transact business abroad. The Securities and Exchange Board of India reports that FEMA develops market regulations based on international best practices. The Securities Contracts Regulation Act of 1956 (SCRA) pertains to all Indian stock exchange participants. The Securities and Exchange Commission is responsible for preventing any unlawful market transactions. The SCRA defines, among other things, derivatives, securities, particular delivery contracts and spot delivery contracts.

Law stated - 28 July 2023

Healthcare arrangements

What regulatory and legal issues commonly arise in relation to healthcare arrangements? What are the main rules and principles that apply to extraterritorial participation in these arrangements?

Pharmaceutical and healthcare personnel in India have their own self-governing conventions, some of which govern drug advertising. The government has issued the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) to promote the voluntary sanction and self-regulation of the Indian pharmaceutical industry. Some pharmaceutical companies have their own internal codes in addition to the UCPMP. The Organization of Pharmaceutical Producers of India, for instance, has its own set of internal regulations known as the OPPI Code 2019.

The Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulations of 2002 govern contemporary medical practitioners in India. Compliance with the 2014 Revised Dentists (Code of Ethics) Regulations is required of dentists. The 2015 Pharmacy Practice Regulations impose a number of regulations on pharmacists. The Homeopathic Practitioners (Professional Conduct, Etiquette and Code of Ethics) Regulations of 1982 govern homeopathic practitioners. Practitioners of Indian medicine (including Ayurveda, Siddha, Unani and Tibb) are required to comply with the Practitioners of Indian Medicine (Standards of Professional Conduct, Etiquette, and Code of Ethics) Regulations 1982.

Law stated - 28 July 2023

COMPETITION, ANTI-CORRUPTION AND TRANSPARENCY RULES

Authority enforcement

Are infringements of competition law by healthcare providers pursued by national authorities?

Yes, by the Competition Commission of India (CCI).

Law stated - 28 July 2023

Private enforcement

Is follow-on private antitrust litigation against healthcare providers possible?

The CCI is the only organisation in India responsible for enforcing competition law. Either on their own initiative or based on information obtained from the CCI, consumers may file civil actions to recover losses or injury caused by anticompetitive conduct. The CCI investigates and adjudicates anticompetitive conduct. Section 53N of the 2002 Competition Act stipulates that the Competition Appeal Tribunal will decide on compensation claims deriving from the CCI's findings.

Law stated - 28 July 2023

Anti-corruption and transparency

What are the main anti-corruption and transparency rules applicable to healthcare providers?

In India, corruption is regulated by the Indian Penal Code of 1860 and the Prevention of Corruption Act of 1988, as amended. The Indian parliament approved additional amendments to the PC Act on 26 July 2018, including provisions for supply-side prosecution. The President approved of the amendments. In addition to the investigative and prosecutorial authorities, the Comptroller and Auditor General and the Central Vigilance Commission have played crucial roles in cases of public interest.

Law stated - 28 July 2023

REGULATION OF HEALTHCARE SERVICES

Licensing authority and process

Which authorities are charged with licensing and regulating patient care facilities and healthcare professionals? What licensing processes apply?

Compliance with the Clinical Establishment Act of 2017 is required. The provinces in India are carrying out this law, which the federal government of India enacted. A one-time registration is required for the use of a building as a hospital. Registration is the responsibility of the state government that enacted this law. If a corporation established the hospital, registration under the 2013 Companies Act is necessary. The statute stipulates that a business must be registered and comply with incorporation requirements, such as a memorandum of association, articles of association, capital structure formation, securities allotment and account audits. If a society wishes to set up a hospital, the Societies Registration Act of 2001 is necessary.

Other necessary licences include the Regulations Building Permit and Licenses (from the municipality); the No

Objection Certificate from the Chief Fire Officer; the Bio-z-Medical Management and Handling Rules, 1998 License; and the No Objection Certificate under the Pollution Control Act 1985 Narcotics and Psychotropic Substances Act; Vehicle Registration Certificates (for all hospital vehicles); Atomic Energy Regulatory Body Approvals (for the radiologist's structural facility); License for the Blood Bank; If applicable, the Transplantation of Human Organs Act of 1994; and the Prenatal Diagnostics Test Act of 1996 (PNDT stands for Prenatal Diagnostics Test). Dentist Regulations 1976; Drugs & Cosmetics Act 1940; Electricity Act, 1998; ESI Act 1948 (for contract employees); Environment Protection Act 1986; Fatal Accidents Act 1855; Guardians and Wards Act, 1855; Indian Lunacy Act 1912 (applicable only if the hospital has a psychiatry department); Indian Nursing Council Act 1947 (registration of nurses with NCI). 1948 saw the passage of the Pharmacy Act, 1989 the SC and ST Act, 1993 the Protection of Human Rights Act, 1969 the Registration of Births and Deaths Act, 1976 the Urban Land Act, and 2005 the Right to Information Act.

There are no restrictions on the categories of healthcare providers authorised to operate in India. Regional and/or zonal health and family welfare departments, which have more divisions than their national counterparts, must enforce the healthcare delivery laws. According to the National Council of Clinical Establishments, the 2010 Clinical Establishments Act mandates compliance with all laws. The National Medical Commission administers and regulates the Drugs and Cosmetics Act, while the Central Drug Standard Control Organization (CDSCO) administers and regulates medical education and practice. Each organisation receives funding from the Department of Health and Family Services. Indian courts can also enforce healthcare laws and regulations, depending on the nature of the case.

It is the responsibility of the Indian Ministry of Health to regulate the healthcare industry. The Directorate General of Health Services functions as a repository for health and medical education-related scientific data. To ensure the safety, efficacy and uniformity of pharmaceuticals, cosmetics, diagnostics and medical devices sold in the United States, the CDSCO develops recommendations and standards. Also governed are the importation and licensing of pharmaceuticals, the certification of new drugs for market release and the requirements for clinical trials. The National Pharmaceutical Pricing Authority modifies the list of medications with limited prices on a regular basis by adding or removing products based on export and import criteria and pharmaceutical company market shares.

It is the responsibility of the National Medical Commission to supervise medical education and ensure equal access to medical facilities. As the primary pharmaceutical regulator in India, the Drug Controller is responsible for a variety of matters, including drug approval and regulation, clinical trials, new product introductions and new import licences. All individuals entering the Indian food industry are required to obtain a licence from the Food Safety and Standards Authority of India. These licences regulate the sale of all special diet foods, supplements, organic foods, functional foods and nutraceuticals in India.

Indian healthcare is regulated by the Ministry of Health and Family Welfare, the Ministry of Ayurveda, the Ministry of Ayush, the CDSCO, Unani, Siddha and Homoeopathy.

Law stated - 28 July 2023

Cross-border regulation

What requirements and restrictions govern the mobility of licensed health professionals across borders?

There are currently no formal regulations. India has proposed creating a global pool of health specialists that any country may call on in the event of pandemics or natural disasters in a submission to the World Trade Organization.

Law stated - 28 July 2023

Collaboration between healthcare professionals

What authorisations are required for collaboration between healthcare professionals? How is this regulated?

In India, the Medical Council of India (MCI) Regulations 2002 restrict healthcare practitioners' relationships with pharmaceutical corporations by establishing guidelines for professional conduct, etiquette and ethics. The MCI Regulations 2002 include all doctor–patient relationships, whether they take place in a hospital or a clinic. They outline doctors' roles in giving the best care possible to their patients. Doctors can be held accountable for any mistakes in hospital therapy and sued under the Consumer Protection Act, tort law, or criminal acts, depending on the severity of neglect and level of patient care. According to sections 6.8 and 6.8.1 of the Code of Conduct for Pharmaceutical and Allied Industries, medical practitioners shall respect and comply with the legal limits outlined in section 1.9 of the MCI Regulations 2002.

Law stated - 28 July 2023

Collaboration between patient care facilities and healthcare professionals

What authorisations are required for collaboration between patient care facilities and healthcare professionals? How is this regulated?

The MCI Regulations 2002 manage contacts between healthcare practitioners and pharmaceutical corporations in India by establishing standards of professional conduct, etiquette and ethics. The 2002 MCI Regulations apply to all doctor-patient contacts, whether they take place in a hospital or a clinic. They define physicians' responsibilities to offer the best possible care to their patients. Doctors can be sued for mistakes in hospital therapy under the Consumer Protection Act, tort law or criminal law, depending on the severity of the neglect and how effectively the patient was cared for.

Law stated - 28 July 2023

Training of healthcare professionals

What educational and training requirements must physicians and healthcare professionals satisfy to obtain the right to practise in your jurisdiction?

The Indian Medical Council Act of 1956 was amended in 2002 regarding professional conduct and ethics. This Act creates and maintains the MCI and the Indian Medical Register, as well as provisions related thereto. The statute was revised in 1964 and 1993. Sections 11, 12 and 13 stipulate that only the MCI in India has the authority to accredit medical institutions, approve new academic programmes, upgrade existing academic programmes and increase the number of qualified students enrolled in any given academic program. Section 15 allows licensed physicians to practise allopathic medicine. Sections 16–20 provide standards for the accreditation of medical institutions and the regulation and upkeep of the integrity of medical education. All medical professionals must adhere to the 'standards of professional conduct, etiquette, and code of ethics' established by the council. All other state medical agencies must comply with these requirements.

Registration, revocation and reinstatement of names, as well as the maintenance and addition of names, were addressed in sections 21–29. In 2002, the MCI informed its members of new professional conduct, etiquette and ethics regulations.

Law stated - 28 July 2023

Discipline and enforcement

What civil, administrative or criminal sanctions, penalties, corrective measures and related tools may be imposed on patient care facilities and healthcare professionals for regulatory non-compliance?

Section 33 of the Clinical Establishment Act of 2010 grants the authority or officer the authority to inspect registered clinical establishments or the work they conduct or perform.

Law stated - 28 July 2023

Patient complaints

How are patient complaints processed and adjudicated?

The inspector investigates complaints filed under the Drugs and Cosmetics Act of 1940 and, upon completion of the report, initiates prosecution in the Session Court. The Criminal Procedure Code of 1973 regulates these types of proceedings.

The Indian Penal Code, 1860 (IPC), can be used to establish criminal liability, but it is overly broad and lacks a section on 'medical negligence'. For instance, cases of rash and negligent motor vehicle driving accidents and cases of medical negligence resulting in a patient's death are handled using the same provision of the IPC, which deals with the death of a person resulting from any rash or negligent act and carries a maximum two-year prison sentence.

Pursuing a remedy in a civil court or consumer forum can help obtain civil liability, ie. monetary compensation, under the general law. If the patient or his family members are still alive, they can sue the negligent doctor or hospital for compensation for the harm they caused. A complainant seeking relief regarding services 'in a hospital or dispensary' that are 'public utility services' within the meaning of the statute may also approach permanent lok adalats established pursuant to the Legal Services Authority Act, 1987, where first conciliation is attempted followed by a determination on the merits. Permanent lok adalats are granted civil court-like judicial powers (such as the power to compel the attendance of witnesses) and jurisdiction over cases with a maximum value of 1 crore rupees.

Additional potential outcomes of medical negligence include disciplinary sanctions. The Indian Medical Council (IMC) Act of 1956, as amended by the IMC (Professional Conduct, Etiquette, and Ethics) Regulations of 2002, governs medical practitioners' professional malfeasance. The MCI and individual state medical bodies have the authority to take disciplinary action, such as revoking or suspending a physician's licence. Nevertheless, medical malpractice is not the only instance of professional misconduct. For example, in the context of lawyers, not only professional misconduct but also other misconduct, such as violation of the prohibition on liquor under the Bombay Prohibition Act 1949, may result in the imposition of disciplinary sanctions, and perhaps a similar principle could be applied to cases of medical negligence by medical professionals.

Law stated - 28 July 2023

DATA PROTECTION, PRIVACY AND DIGITAL HEALTH

Responsible authorities and applicable legislation

Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation?

In India, data protection and privacy laws are undergoing revisions. The Information Technology Act 2000 (IT Act) and the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules 2011 are India's primary data protection and privacy laws. In addition to the Consumer Protection Act of 2019 and the Consumer Protection (E-Commerce) Rules of 2020, there are additional ancillary and sector-specific regulations, such as the Information Technology (the Indian Computer Emergency Response Team and the Manner of Performing Functions and Duties) Rules 2013, the directions imposed by the Indian Computer Emergency Response Team and rules published by regulatory authorities in India, such as the Reserve Bank of India.

In response, the Indian government introduced the Personal Data Protection Bill (PDP Bill) to the lower house of the Indian parliament in 2019. The PDP Bill differed significantly from the Srikrishna Committee's draft bill in a number of important ways, such as the relaxation of the data localisation requirements, the inclusion of a right to deletion, the inclusion of the concepts of consent management and privacy by design, etc. The measure was referred to a joint committee for roughly two years of deliberation. The revised PDP Bill, now known as the Data Protection Bill 2021, was introduced in the Indian parliament alongside the joint parliamentary committee's report. The Indian government withdrew the PDP Bill from parliament in 2022, citing the joint parliamentary committee's recommendation for significant amendments. The Indian government is contemplating the introduction of a new measure that would provide an all-encompassing framework for the promotion of the digital economy.

The Indian government issued a draft of the Digital Personal Data Protection Bill 2022 (the DPDP Bill) for public comment in 2022; the final version would be presented to parliament in 2023. The current iteration of the DPDP Bill, which seeks to update and implement key provisions of the preceding Indian data privacy legislation, is much simpler than its predecessors. If the DPDP Bill becomes law, it will include several significant new provisions that could have far-reaching effects on the tech industry, digital firms, entrepreneurs and even the general public.

Law stated - 28 July 2023

Requirements

What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

The DPDP Bill imposes obligations on data custodians primarily in the following areas:

- safeguarding collected personal data;
- notification requirements in the event of a data breach;
- restrictions on personal data storage when the purpose for such data is no longer served or retention is not required for legal or business purposes;
- appointment of a data protection officer to respond to questions from data principals; and
- establishment of a grievance mechanism.

Law stated - 28 July 2023

Regulatory guidance

Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

The DPDP Bill is based on the following concepts: legal, transparent and equitable application of data-by-data principles; legal purpose; data minimisation; suitable safeguards; storage limitations; data accuracy; and accountability. The current DPDP Bill addresses the way India handles digital personal data collected online from data principals and

offline but digitised. The DPDP Bill extends extraterritorial jurisdiction to data processed outside India for the purpose of profiling Indian data subjects or providing them with products or services.

The DPDP Bill aims to establishes 'deemed consent' from data owners. In the following situations, it is reasonable to expect the data subject to voluntarily disclose their personal information to the data trustee:

- when the data principal provides personal data voluntarily to the data fiduciary and such personal data is required for the performance of any law or the provision of any service or benefit to the data principal; and
- when the data principal is required to provide personal data to comply with any judicial order. The 'consent manager' enables individuals to examine, revoke and monitor their consent.

The DPDP Bill established the consent manager, a data principal-responsible corporation registered with the appropriate government agency. The DPDP Bill expands data subjects' rights to include:

- the right to obtain a summary of the personal data processed and the identities of all data fiduciaries with whom such data has been shared;
- the right to correct or erase their personal data;
- the right to grievance redress; and
- the right to nominate a nominee to exercise their rights if they are physically or legally unable to do so.

The DPDP Bill mandates parental or legal guardian consent for the collection and processing of children's personally identifiable information. The data trustee cannot monitor minors or market to them. The DPDP Bill distinguishes between common and essential data custodians. The government informs organisations that process a significant amount of sensitive personal data that they are stewards of vital data. The government may require big data custodians to conduct a data protection impact assessment, quarterly audits and an independent data auditor to determine compliance with the DPDP Bill and IT Act. The DPDP Bill does not effectively enforce data localisation regulations by allowing data transfers to countries notified by the Indian government under terms and conditions established by the government. The DPDP Bill establishes a data protection board to investigate complaints from data subjects, meet the requirements of data principals and hold data stewards accountable for legal violations. The council has not been chosen by the government. The DPDP Bill authorises the board to subpoena witnesses, interrogate them under oath and review any data, book, document, register, books of account or other document to investigate the compliance of data fiduciaries with the law. Infringements on the DPDP Bill can result in a penalty of 2.5 billion rupees.

Law stated - 28 July 2023

Common infringements

What are the most common data protection and privacy infringements committed by healthcare providers?

The government and Ministry of Health and Family Welfare (MoHFW) announced the National Digital Health Mission and published a blueprint recommending the creation of a National Digital Health Ecosystem to facilitate interoperability between digital health systems at the patient, hospital and ancillary healthcare provider levels by the end of 2019. MoHFW issued the Health Data Management Policy (HDM Policy) for the ecosystem on 14 December 2020, citing the Personal Data Protection (PDP) Bill as its primary legal precedent. The HDM Policy recognises both fiduciaries (similar to controllers under GDPR) and data processors (similar to the PDP Bill) and establishes an authorisation structure for processing personal data for use in health data management.

Healthcare practitioners violate Chapter II of the Personal Data Protection Bill 2019 if they create, obtain, store, distribute or reveal digital health information without patient consent. Whoever improperly stores digital health information, including information that has not been anonymised or de-identified or therapeutic data, will be held accountable.

The Indian government withdrew the PDP Bill 2019 from Parliament on 4 August 2022. Since 2019, the law has been pending in the House of Representatives, and a Joint Parliamentary Committee has just completed a comprehensive report on it. The withdrawal demonstrates the government's need to reconsider the scope and organisation of data regulation. The administration has hinted that this is one of four upcoming pieces of legislation encompassing topics such as social media, digital technology, telecommunications and privacy. The administration would rather adopt sector-specific laws as opposed to a comprehensive law that covers all aspects of digital technology. A new statute that is part of a wider legal framework would also replace the PDP law.

In India's Penal Code from 1860, two of the many concepts defined are dishonesty and fraud. Anyone convicted of a severe healthcare information violation faces a minimum fine of 500,000 Indian rupees and a maximum prison sentence of three to five years. Depending on the judge's decision, the injured party may receive compensation from the fine.

The Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules of 2011 and sections 43A and 72A of the Information Technology Act of 2000 govern data protection in India. Section 43A addresses damages for insecure data, while section 72A addresses penalties for disclosures that do not comply with the law's content requirements. Section 72A violations are punishable by up to three years in detention and/or a fine of up to five million rupees. The Information Technology Rules of 2011 require businesses to obtain consent before disclosing any personally identifying information.

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Digital health services

Which authorities regulate the provision of digital health services and what is the applicable legislation? What basic requirements are placed on healthcare providers when it comes to digital health services?

In India, only a few laws, norms and standards govern digital health. Despite the fact that each digital health tool or business model is administered differently, there are restrictions that apply to all digital health technology. Relevant pieces of legislation include the Information Technology Act of 2000, the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data and Information) Rules of 2011 (SPDI Rules), and the Information Technology (Intermediaries Guidelines) Rules of 2011 (Intermediaries Guidelines). The IT Act, the SPDI Rules and the Intermediary Guidelines constitute India's comprehensive data protection system. Due to the IT Act's enhanced security measures, online transactions and electronic data transfers are now authorised. The IT Act regulates a vast array of online activities, including the authentication of digital signatures and the legal standing of electronic information. The IT Act addresses numerous cybercrimes, including hacking and denial-of-service attacks.

The Information Technology Act of 2000 and the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules of 2011, which provide some protection for the collection, disclosure and transfer of sensitive personal data such as medical records and histories, govern India's current legal framework for e-health protection. In contrast, legislation has lagged behind technological advancements and neglected to address a number of critical issues. Consequently, an increasing number of medical institutions and healthcare providers in India store patient information in electronic medical records (EMRs) and electronic health records (EHRs). The Clinical Establishments (Registration and Regulation) Act of 2010 mandates that every clinical institution maintain an EMR for every patient whose registration must be maintained. The Ministry of Health and Family

Welfare first published the EHR Standards in 2013. In December 2016, they were revised and made accessible.

EHR Standards are a collection of international standards that healthcare professionals can use in the creation and upkeep of electronic health records. Some of the MoHFW's most important ongoing digital health projects are Reproductive Child Healthcare, Integrated Disease Surveillance Program, Integrated Health Information System, e-Hospital, e-Shushrut, Electronic Vaccine Intelligence Network, Central Government Health Scheme, Integrated Health Information Platform, National Health Portal, National Identification Number and Online Registration System.

These programmes are well established in the medical industry and continue to generate vast quantities of data that can be used for the public's benefit. The National Health Mission (helps states pay for connected services such as telemedicine, teleradiology, tele-oncology, tele-ophthalmology and hospital information systems because health is a state responsibility.

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UPDATE AND TRENDS

Key developments

Are there any current or foreseeable legislative initiatives, court cases, laws or other rules that affect the regulation of healthcare? What has recently changed (or will likely change), and what steps need to be taken in preparation?

The government of India has prompted fundamental adjustments and interventions at the policy level to ensure health equity. As a crucial step towards UHC, the National Health Policy (NHP) 2017 is a prescription to resolve existing and emerging socioeconomic and epidemiological challenges. Aligned with the objectives of the 2017 National Health Policy, the government of India (established Ayushman Bharat (AB) with two key components, signifying a transitional shift in the prioritisation of policies and programmes to achieve universal healthcare. The AB Health and Wellness Centers serve as a platform for the delivery of Comprehensive Primary Health Care, with referral hospital connections. Telemedicine, point-of-care diagnostics, medical virtual assistants, robot-assisted surgery, self-monitoring devices, big data in healthcare, electronic health records, e-pharmacies and the management of health data are among the new concepts emerging in India, for which regulations are expected to be formulated shortly.

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Jurisdictions

Australia	Clayton Utz
Canada	Stikeman Elliott LLP
India	LexOrbis
Ireland	Matheson LLP
Italy	CMS Italy
Japan	Anderson Mōri & Tomotsune
Mexico	OLIVARES
Sweden	Cirio Advokatbyrå AB
Turkey	Gün + Partners
USA	Norton Rose Fulbright