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The Anatomy of India's Healthcare Sector

Understanding the Legal and Regulatory Landscape



Foreword

Indian healthcare has traversed a remarkable arc. A country from which patients once travelled abroad in search of advanced treatment has, through sustained ambition and a bold vision of accessible, quality care, become a global destination for medical excellence. That journey is far from complete.

Healthcare can no longer begin and end with a hospital visit. It must progress from episodic treatment to a system that places holistic prevention at its core. That transition is already visible. Artificial intelligence and continuous health monitoring are enabling the early detection of risk, often long before illness takes hold. India must embrace this digital revolution with conviction and build devices and algorithms attuned to the needs and characteristics of Indian populations. We are well placed to do so. Our telecom connectivity, insurance coverage and engineering talent provide a formidable foundation for scaling wearable-led preventive care, and the size of our market allows development costs to be distributed across a wider ecosystem.

For our healthcare ecosystem to capitalise fully on these advances, and to ensure their benefits reach citizens, a nuanced understanding of the evolving legal and regulatory landscape is imperative. Regulation is changing at a striking pace as it seeks to keep abreast of rapidly advancing technologies and rising demand. Sustained engagement with government and regulatory authorities is equally essential.

The Indian government has taken significant steps to fortify the healthcare sector. The Ayushman Bharat Digital Mission and eSanjevani are bridging hospitals, digital platforms and home-based care, while PM-JAY, microinsurance and healthcare lending are proving vital to affordability and to extending care to Tier-2 cities and underserved communities. Greater incentives for domestic medical device manufacturing would lend further impetus to an industry of considerable promise.

Looking ahead, digital adoption, accountable care models and innovative financing will emerge as the principal levers of growth.

NATHEALTH is delighted to collaborate with Khaitan & Co on this compilation of expert perspectives, which offers a deep overview of the legal and regulatory landscape for India's integrated healthcare, life sciences and medical devices ecosystem. I look forward to the thoughtful discussions it will inspire.



Dr Sangita Reddy

President, NATHEALTH

Joint Managing Director, Apollo Hospitals Group



Preface

From traditional healing practices and early medical sciences, to telemedicine, advanced medical technology and AI-assisted diagnostics, India's healthcare sector has undergone an extraordinary transformation. The sector has evolved beyond conventional healthcare delivery to encompass areas such as medical tourism, digital health, biotechnology and elder care, and there is a pressing need for nuanced legal, regulatory and tax guidance.

The intersection of rapid technological developments and healthcare advancements has given rise to new opportunities in the areas of access and innovation, but it has also resulted in a rise in complexity.

Article 21 of the Constitution of India, read with numerous judicial precedents, establishes the fundamental right to life, underscoring the paramount importance of preserving human life through timely and adequate medical treatment, as well as access to appropriate healthcare infrastructure. While public health and hospitals fall within the State List (Entry 6) of the Seventh Schedule to the Constitution, key aspects such as drugs, medical education, medical professions, and inter-state contagious diseases are governed under the Concurrent List.

This shared constitutional responsibility has led to the development of various policies and legislative frameworks within the healthcare sector, including the Ayushman Bharat Digital Mission, the National Health Mission, and the National Medical Commission Act, 2019.

Today, healthcare extends far beyond traditional patient care. It encompasses medical technologies, e-consultations, significant advancements in the medical devices sector, corporate social responsibility (CSR) initiatives focused on public health, and environmental, social and governance (ESG) obligations relating to operations and biomedical waste management.

It also includes considerations on land use and zoning for healthcare facilities, as well as the growth of specialised services such as elderly care, maternity and child healthcare, oncology, and other focused disciplines. Additionally, the sector addresses employment-related health requirements, including the appointment of medical officers in factories, establishment of occupational health centres, periodic medical examinations, and broader employee welfare measures.

This resource is a curated collection of perspectives by the Khaitan & Co's legal professionals across multidisciplinary teams, covering corporate, employment, real estate, regulatory, tax, and dispute resolution practices.

Each section examines a critical aspect of the healthcare landscape, including medical tourism, elderly care, telemedicine, artificial intelligence (AI) and its applications, foreign investment trends, mergers and acquisitions structuring, ESG compliance, recent legal developments in medical technologies and devices, taxation frameworks, corporate social responsibility, and real estate considerations within the sector.

The purpose of this compilation is to provide readers with a holistic understanding of the legal and regulatory nuances shaping the integrated healthcare, life sciences, and medical devices ecosystem. These insights are intended to foster meaningful dialogue among stakeholders, support investors seeking to enter the sector, and assist other key participants in navigating its evolving landscape.



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BUSINESS AND **OPERATIONS**





01

Private Funding in Healthcare and Health-Tech

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Private capital's increasing interest in healthcare and health-tech is unsurprising. Rising chronic disease burdens, aging populations, and an overall push towards higher healthcare spending, particularly in digital and remote-care models such as telemedicine, have made the health-tech sector an attractive investment theme.

For private investors, the appeal is twofold. In addition to being a structurally expanding market (especially in countries like India), health-tech enables scalable, asset-light business models that differ materially from

traditional healthcare delivery. Digital diagnostics, virtual disease management, AI-driven imaging, and technology-led supply-chain solutions allow for faster growth with significantly lower capital intensity.

On the flip side, the sector remains exposed to broader geopolitical and trade policy shifts, which may influence tariffs, supply chains, and cross-border capital flows, thereby affecting funding conditions and overall industry stability. This is evident in recent developments related to geopolitical tensions in West Asia and tariff actions by the United States of America (USA) on certain healthcare imports, underscoring how such events can translate into near-term volatility and long-term effect for health-tech businesses.

Despite this, health-tech funding has shown steady growth, in part also due to its alignment with the priorities of institutional investors, with many increasingly looking for strategies that deliver both competitive returns and measurable social impact. Improved access to care, cost efficiency, and outcome-driven interventions make the sector naturally ESG-positive, further garnering LP interest.

Reflecting this momentum, the Indian healthcare sector has recorded approximately USD 14.5 billion in private equity / venture capital investments since 2020, with USD 1.9 billion flowing specifically into health-tech startups. Much of this capital has been deployed through specialist private investment vehicles, such as HealthQuad Fund III, launched by the Quadria Group last year, ChrysCap Fund, and such other healthcare and health-tech focussed funds.

In fact, data published by Securities and Exchange Board of India (SEBI) indicates that over INR 22,500 crores has been invested in pharmaceuticals, and nearly INR 15,000 crores has been routed to healthcare providers and services, by AIFs. Examples include ChrysCap's investment in La Renon, a generics company, and KKR's exit from JB Chemicals at a 5x valuation in just about 5 years.

Private Funds: A Strong Structural Fit for Health-Tech Investments

Private funds provide a strong structural fit for health-tech investments for several reasons.

Long Fund Life

SEBI does not prescribe a statutory cap on fund tenure. Close-ended funds only need to specify a fixed term and ensure that extensions comply with applicable limits. While fund tenures of 8 - 10 years are common, managers investing in health-tech may opt for longer durations to account for regulatory hurdles and market integration timelines.

Under the SEBI (Alternative Investment Funds) Regulations, 2012 (AIF Regulations), fund terms may typically be extended by two years with investor consent, and in the case of Large Value Funds (LVFs) extensions of up to five years are permitted. These fairly-flexible terms on private fund tenures align well with health-tech-focused funds, where value creation and respectable exits may require longer gestation.

Growing Market for Secondaries

Although SEBI's approach to limiting fund extensions is intended to protect investors in an inherently illiquid asset class, this structure can reduce flexibility at the time of liquidation, especially when liquidity conditions differ from those anticipated at fund inception. However, the rapid growth of the secondary market in India has significantly eased this constraint. GP-led secondaries, continuation vehicles, and structured liquidity solutions now allow managers to hold high-conviction assets for longer while simultaneously offering early liquidity to investors.

In response to industry demand, SEBI has also experimented with and introduced liquidity mechanisms, ranging from liquidation schemes to the current dissolution period framework, which allows funds to raise patient long term capital and take additional time (subject to investor approval) to wind down assets in an orderly manner.

Rise in Exit Options

Health-tech investors today have a broader set of exit pathways than ever before. Beyond traditional strategic M&A and IPOs, the sector has seen:

- **Continuation funds** enabling GPs to retain high-performing assets
- **Secondary sales** to global health-tech and growth-equity investors
- **Platform consolidation plays** where larger hospital, diagnostics, or med-tech groups acquire technology-led solutions
- **Sponsor-to-sponsor exits**, particularly as generalist funds increase exposure to healthcare

This multiplicity of exit routes provides greater confidence around liquidity and value realisation.

No Sectoral Diversification Requirement

The AIF Regulations do not impose any sectoral diversification requirements, allowing managers to create fully health-tech-focused funds, if desired. Conversely, managers may choose to diversify across strategies (e.g., digital health, med-tech, diagnostics, services) to balance risk. The only mandatory diversification requirement is at the portfolio level, where AIFs must invest in a minimum of four portfolio companies. This requirement reduces to two for LVFs, providing added flexibility for larger-ticket, concentrated health-tech strategies.



Flexible Investment Avenues and Capital Deployment

Investment flexibility is a key advantage of the AIF framework. Funds can invest through a wide array of instruments, including listed or unlisted equity, debt, and equity-linked securities, depending on commercial and industry requirements.

Equally important is the flexibility surrounding follow-on investments, investment through reserves, and reinvestment of proceeds, which is typically governed by fund documents and a balance between LP-GP expectations rather than regulatory prescription. Managers may also negotiate the flexibility to invest both during the commitment period and in limited circumstances, thereafter.

Co-Investment Ability

Co-investments have become a central feature of the Indian private capital landscape, and SEBI has recently expanded the scope for LPs to make additional, direct investments alongside the fund. This development has been widely welcomed by the industry, as co-investments enhance LP involvement; allow investors to increase exposure to high-performing assets; and allow GPs to develop and maintain relationships with both, their LP as well as their portfolio bases.

For health-tech portfolio companies, which often require substantial capital or experience rapid scaling, access to co-investing LPs can provide a significant competitive edge. Certain larger strategic players invest into funds just to get access to co-investment rights and have a strategic and meaningful investment in portfolios.

Access to Industry Expertise

Given the technical and regulatory complexity of health-tech investments, fund managers often establish advisory committees or expert panels comprising industry specialists. The AIF framework permits significant flexibility in designing these governance bodies. Such structures help guide investment and divestment decisions and are increasingly viewed by LPs as essential for specialist strategies like health-tech.



Conclusion

The intersection of rising healthcare demand, rapid digital adoption, and a flexible AIF regime has made health-tech a natural fit for private capital. With maturing exit markets and increasingly sophisticated fund structures, private funds are well placed to back the next generation of health-tech leaders in India.



02

Debt Financing in the Healthcare Sector

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India's healthcare sector continues to require substantial long-term and short-term capital across hospitals, diagnostics, medical devices, healthcare infrastructure and technology-enabled care delivery. Healthcare businesses are asset-heavy and require periodic capital expenditure and working capital support to manage receivable cycles, procurement obligations and regulatory compliance costs. Accordingly, debt financing remains an essential funding tool for the sector.

The principal modes of debt financing available to the healthcare sector in India are highlighted below.

Bank Term Loans, Project Financing and Asset Financing

Banks and financial institutions typically provide term loans and working capital facilities with scheduled repayment obligations, security over project and business assets, and detailed financial and operational covenants. Banks also provide working capital support through cash credit facilities, overdraft facilities, working capital demand loans, bill discounting, and receivables-backed limits.

Term loan provided by lenders for financing of a project may permit moratorium on repayment obligations during construction and ramp-up. The lenders may insist on promoter infusion of certain portion of the total project cost. Further, lenders also provide term loans for purchase of identified asset, with the lender taking security over the financed equipment. Depending on the financing model, the lender may also seek collateral support, assignment of insurance proceeds and negative covenants restricting transfer or further encumbrance.

Banks usually require security to be created over the assets of the borrower which typically include mortgage over land and buildings, hypothecation over plant, machinery and medical equipment, hypothecation over inventory and receivables, pledge over shares and charge over bank accounts and cash flows. Such security may be required to be registered with the Registrar of Companies and the relevant sub-registrar.

Banks and financial institutions generally subject borrowers to certain financial covenants such as maintenance of debt service reserve account, debt to equity ratio, minimum security cover, debt service coverage ratio and interest service coverage ratio. Additionally, operational covenants such as utilisation of the loan proceeds, end use restrictions, control of the borrower, continuation of material contracts are also regulated by the bank.

Non-Convertible Debentures and Listed Debt Securities

Established healthcare groups in India may access debt capital markets by issuing non-convertible debentures (NCDs), whether on a privately placed basis or through public issuance. NCDs issued by companies may be subscribed to by banks, non-banking financial companies, foreign portfolio investors, alternate investment funds, mutual funds, insurance companies and other body corporates.

For the purpose of issuance of NCDs, a borrower is required to appoint a debenture trustee who is a person registered with SEBI under the SEBI (Debenture Trustees) Regulations 1993 who acts for and on behalf of the debenture holders.



Where secured NCDs are issued, the debenture holders usually require security to be created over the assets of the borrower which typically include mortgage over land and buildings, hypothecation over plant, machinery and medical equipment, hypothecation over inventory and receivables, pledge over shares and charge over bank accounts and cash flows. Such security may be required to be registered with the Registrar of Companies and relevant sub-registrar.

Further, borrowers may be subject to certain financial covenants such as maintenance of debt service reserve account, debt to equity ratio, minimum security cover, debt service coverage ratio and interest service coverage ratio. Additionally, operational covenants such as utilisation of the loan proceeds, end use restrictions, control of the borrower, continuation of material contracts are also regulated by the debenture holders.

Acquisition Financing

Banks in India are permitted to provide acquisition financing to eligible Indian non-financial company (including its subsidiary and step-down special purpose vehicle). Acquisition finance is a financial facility or assistance provided to an eligible borrower for acquiring shares in a target where the transaction results in the borrower acquiring control over the target. Such borrower needs to have a minimum net worth of INR 500 crores, net profit after taxes reported in each of the previous three consecutive financial years and in case the borrower is an unlisted company then the borrower is required to have an investment grade rating (BBB-).

In such transactions, banks can provide financing up to 75% of the acquisition value and balance 25% is required to be funded by the acquiring entity through its own funds such as internal accruals or fresh equity. Such acquisition financing needs to be secured primarily by way of pledge over the acquired shares and corporate guarantee from the acquiring company, or its parent or group holding entity. Additional collateral may be provided in the form of security over the unencumbered assets of the acquirer or the target. The borrowers are required to ensure that the debt-to-equity ratio at the acquiring company level does not exceed 3:1 on a continuous basis and minimum-security cover.

External Commercial Borrowings

For larger Indian healthcare businesses, external commercial borrowings (ECB) can provide access to offshore debt for permitted purposes, subject to the Reserve Bank of India's (RBI) ECB framework. The ECB framework in India is governed primarily by the Foreign Exchange Management Act 1999 read with the regulations framed thereunder (FEMA). ECB may be raised in any form of commercial borrowing arrangement that involves payment of agreed interest, if any, by whatever name called, and repayment of principal.

Any person resident in India (except individuals) incorporated, registered or established under Indian laws is eligible to raise ECB. ECB can be provided by all persons that reside outside India (including individuals), overseas branches and subsidiaries of entities whose lending business is regulated by RBI and financial institutions or their branches in International Financial Services Centre. The borrowing limit for raising ECB is up to the higher of either outstanding ECB up to USD 1 billion; or total outstanding borrowing up

to 300% of net worth as per the last audited standalone balance sheet of the borrower including the proposed ECB. However, the ECB framework contains certain end-use restrictions including in relation to construction and development of hospitals.

ECBs may be raised in any foreign currency or INR and are not restricted to just freely convertible currencies. The cost of borrowing of the ECB is required to be in line with prevailing market conditions. The borrowers are required to file relevant forms with the Authorised Dealer bank making relevant disclosures as required by the RBI.

Conclusion

Debt financing remains central to the growth of India's healthcare sector. The legal analysis of debt financing must go beyond standard corporate and security documentation. It must also address FEMA considerations where offshore debt is involved, Companies Act 2013 requirements for borrowing and charge registration, SEBI rules for listed debt, insolvency risk under the Insolvency and Bankruptcy Code 2016 and the healthcare-specific regulatory framework applicable to the borrower's operations.

A well-structured debt package can support expansion and operational resilience without ownership dilution. However, the success of such financing depends on disciplined structuring, robust due diligence and careful alignment between the borrower's cash flows, regulatory status and security profile.





03

Hospital Operations and Management Agreements: Market Structures, Drivers and Legal Architecture

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India's healthcare sector faces a well-documented structural paradox: although substantial hospital infrastructure exists across the country, including facilities owned by trusts, societies, charitable and religious institutions, public bodies and family-owned hospitals, yet much of it remains underutilised, poorly maintained or operationally sub-scale. At the same time, private hospital chains seeking rapid expansion face prohibitive land acquisition costs, lengthy construction timelines and complex local licensing processes.

The past decade has seen hospital operations

& management (O&M) agreements emerging as a contractual mechanism that bridges this gap, serving the complementary interests of two distinct parties: owners and operators.

Owners hold valuable land and hospital assets but frequently lack the capital, management capacity or clinical expertise required for modernisation leading to outdated infrastructure, low occupancy, weak management and poor revenues of such hospital assets. Operators, generally large private hospital networks, seek brownfield expansion opportunities that offer speed to market without substantial upfront capital commitment. The O&M agreement enables the owner to monetise and revitalise its institution without compromising ownership or charitable objectives, whilst affording the operator comprehensive operational control over an existing facility.

Conceptualising O&M in the Indian Healthcare Sector

A hospital O&M agreement is a long-term arrangement under which the owner retains title to land and buildings, whilst granting the operator exclusive rights to operate, manage and maintain the hospital. Terms generally range from 10 to 30 years or more. The operator exercises comprehensive control over clinical and non-clinical operations, including staff engagement, equipment procurement, vendor management, tariff setting and quality assurance. Owners retain oversight through governance committees and reserved matters.

An O&M agreement is distinguishable from departmental outsourcing arrangements, under which hospitals routinely outsource individual clinical or non-clinical services (such as radiology, laboratory and diagnostics, dialysis, biomedical equipment maintenance, housekeeping, kitchen, laundry, pharmacy or ambulance services) to specialised vendors. By contrast, an O&M agreement entails the delegation of comprehensive operational control over the entire hospital, or a defined block of the hospital, to a single operator. However, in certain structures, an O&M arrangement might also involve the owner retaining some of these clinical or non-clinical services with the operator assuming overall control over the hospital's operations.

Regardless of nomenclature — whether termed management agreement, services agreement or lease-operate contract — O&M structures share the following consistent features:



- Operational autonomy lies with the operator
- Ownership, public obligations and legacy regulatory permissions remain with the owner
- The commercial construct typically combines management fees, revenue sharing and minimum guarantees
- The agreement expressly disclaims any partnership or joint venture

Market Context: Drivers and Use Cases

Owners with Underutilised Hospital Assets: Turnaround of Legacy Institutions

Many Indian hospitals are owned by trusts or societies that hold valuable real estate and community goodwill but lack the resources to modernise infrastructure or manage multi-speciality services. These institutions — often long-standing charitable or family-run hospitals — face operational distress arising from outdated infrastructure, weak governance, poor revenue cycle management, compliance gaps and insufficient working capital.

O&M arrangements enable owners to monetise and revitalise these institutions without compromising ownership or charitable objectives. Operators bring modern equipment, clinical governance, requisite accreditation (from the National Accreditation Board for Hospitals & Healthcare Providers (NABH) and the National Accreditation Board for Testing and Calibration Laboratories (NABL)), financial discipline and adequate working capital to facilitate a comprehensive operational turnaround.

Similarly, many government hospitals, public health centres and diagnostic centres face chronic gaps in equipment maintenance, skilled manpower, modern technology and quality standards. O&M contracts allow government authorities to leverage private sector expertise to upgrade and operate services efficiently.

Asset-Light Expansion and Corporate Network Growth

Private hospital chains prioritise rapid brownfield expansion to grow their network footprint without committing substantial capital. O&M structures allow an operator to enter and operate an existing hospital facility with minimal upfront investment, whilst exercising control over the hospital's day-to-day operations, staffing, branding and service delivery. This enables operators to scale into multiple geographies — particularly tier 2 and 3 cities — without undertaking the time-consuming and capital-intensive process of acquiring land, constructing new facilities or navigating local licensing hurdles.

Among private hospital chains, O&M arrangements are increasingly deployed as a strategic tool to build regional clusters, establish satellite centres in adjoining towns, integrate smaller hospitals into referral networks and improve brand visibility with minimal capital expenditure.



Public and Charitable Restrictions

Hospital properties allotted by governmental authorities, municipal bodies or development authorities are often governed by charitable objects and carry restrictions that prevent alienation or conversion by way of sale or lease. O&M structures allow private operators to modernise, manage and operate the hospital without changing ownership, land use character or the institution's public or charitable nature. This ensures continued compliance with obligations such as free or subsidised beds, economically weaker sections quotas and similar requirements.

Tax and Compliance Considerations

For charitable hospitals, maintaining tax-exempt status under Section 332 of the Income Tax Act, 2025 ("Income Tax Act") (Section 11/ Section 12 of the erstwhile Income Tax Act, 1961) is critical. The principal risk is that the arrangement may be characterised as the trust carrying on a business, or that the income derived from the O&M arrangement may be treated as a diversion of income at source rather than an application of income for charitable purposes — either of which could jeopardise exemption.

The stricter compliance requirements in relation to renewal of registration under Section 332 of the Income Tax Act (Section 12AB of the erstwhile Income Tax Act, 1961) have made it even more critical for trusts to demonstrate active supervisory control over their operations. Common safeguards in O&M agreements include arm's length commercial terms; clear delineation of the roles of the parties; and a supervision framework comprising governance committees and reserved matters designed to evidence that the trust continues to exercise supervisory control consistent with its fiduciary duties. As a result, operators can retain operational control with the charitable owner preserving eligibility for tax exemptions, whilst still permitting private expertise in day-to-day management.

From a goods and services tax (GST) perspective, the O&M fee payable to the operator constitutes a supply of services attracting GST at the applicable rate. However, healthcare services provided by the operator directly to patients are exempt under Entry 74 of the GST Exemption Notification (Notification No. 12/2017 — Central Tax (Rate), dated 28 June 2017). The characterisation of specific payment streams such as management fees, revenue share, minimum guarantees and reimbursements must be carefully analysed to determine the applicable GST treatment. Minimum guarantees, deposits and fee structures are frequently influenced by these tax considerations.

Risk Ring-Fencing and Owner Protection

A primary driver for contemporary O&M structuring is the insulation of the asset owner (individual trustees in case of a trust) from the inherent liabilities of clinical care. Typically, O&M agreements contractually allocates operational, employment and medico-legal risks to the operator, creating a 'risk ring-fence'. This is reinforced by a robust indemnity framework and the mandatory maintenance of professional indemnity and medical malpractice insurance by the operator at agreed coverage limits. However, the owner indemnifies the operator for any pre-existing liabilities and historical non-compliances attributable to the owner, prior to the operator's entry.

The delegation of authority through the O&M agreement is designed to ensure that owners have no personal exposure beyond their statutory fiduciary duties. This protection is contingent on the owner maintaining a clear framework of oversight and periodically benchmarking the O&M fee to ensure arm's length pricing.

Teaching and Charitable Hospitals Seeking Controlled Expansion

Medical colleges, teaching hospitals, missionary institutions and charitable trusts often seek to expand service offerings through private players. In such arrangements, owners wish to preserve teaching, charitable work and training programmes, whilst private operators run new multi-speciality or super-speciality blocks, oncology centres or diagnostics complexes under jointly agreed protocols. O&M structures ring-fence legacy functions whilst enabling modernisation, cross-utilisation of clinical faculty for the attached medical college, compliance with National Medical Commission norms and preservation of the institution's mission, religious ethos or charitable status.

Structural Archetypes of O&M Arrangements

Hospital O&M agreements in India may broadly be categorised into five structural archetypes, i.e., pure management fee, revenue sharing, lease and operate, public-private partnership and hybrid or bifurcated models. Although, in practice, most agreements represent hybrid structures combining elements from multiple categories.



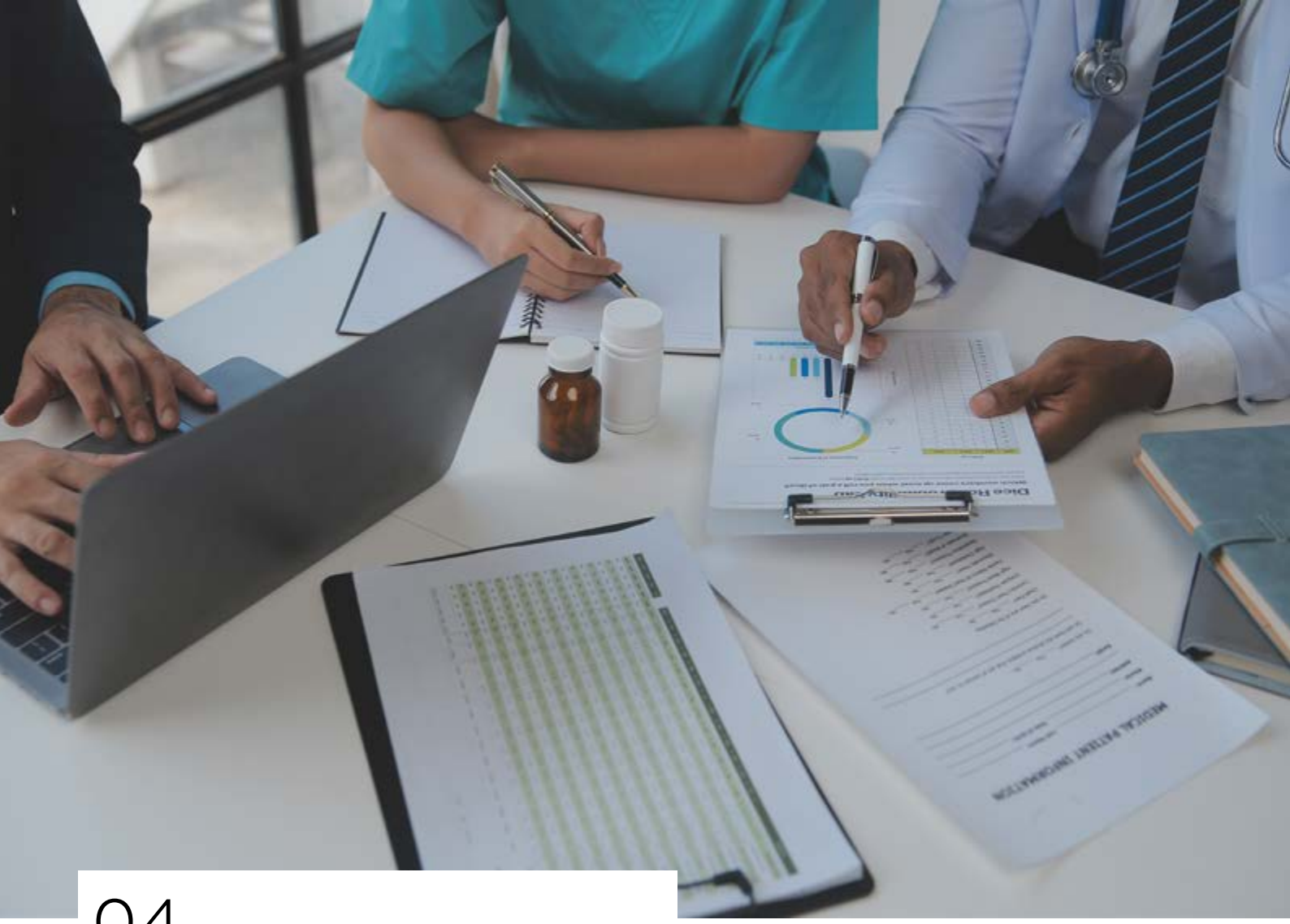
Conclusion

Hospital O&M agreements in India have evolved into a sophisticated contractual mechanism that blends elements of outsourcing, revenue sharing, long-term asset use and strategic collaboration. They allow private operators to assume end-to-end operational responsibility whilst preserving ownership, public obligations and charitable identity for existing institutions.

Although market practice reflects broad commonalities, O&M structures remain highly sensitive to ownership profiles, land-use restrictions, licence transferability and the parties' relative bargaining strength. Increasingly, O&M arrangements are being designed not merely as operational contracts but as scalable platform structures capable of attracting private equity investment and eventual public market participation. As this evolution continues, the emphasis will shift towards auditability, ring-fencing of risk, arm's length governance and investor-grade compliance frameworks.

When drafting or negotiating these agreements, the key challenge lies in calibrating operational autonomy against regulatory and charitable constraints, structuring commercial incentives that remain viable over long tenures, and allocating risk in a manner that is enforceable under Indian law. Special care is required in drafting governance frameworks, licence arrangements, non-compete covenants, indemnity packages and exit mechanisms, given the high degree of judicial scrutiny applied to healthcare operations and restraints of trade.

As O&M models continue to expand across private and public healthcare settings, greater clarity from regulators on issues such as license ownership, charitable obligations and land-use compliance would significantly enhance certainty and reduce friction in transactions. Until such clarity is provided, robust drafting, thorough due diligence and careful negotiation remain essential for ensuring that O&M agreements achieve their intended balance of operational efficiency, legal compliance and long-term commercial viability.



04

Succession Planning for Owners of Healthcare and Hospital Business: Preventive Medicine Approach to Ownership and Legacy

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Succession planning within the Indian healthcare sector requires a degree of legal, regulatory and governance rigour not ordinarily demanded of other industries. Hospitals and healthcare institutions operate within heightened fiduciary, ethical and statutory expectations, owing to the public-facing and trust-dependent nature of their services. Their obligations extend beyond commercial performance to encompass clinical safety, continuity of patient care, infrastructure reliability, and adherence to a wide matrix of regulatory regimes.

In this environment, the authority and credibility of founders, promoters and senior clinical leaders form a critical part of the institution's functional stability. Consequently, the sudden incapacity or death of such individuals does not simply trigger financial transition but can materially affect governance structures, clinical oversight, employee confidence, compliance status and public trust. Succession planning in healthcare therefore constitutes a fundamental element of organisational risk mitigation and cannot be deferred or left to default inheritance or corporate mechanisms.

Planning for the Inevitable: The unique crossover between healthcare and succession

The absence of a clearly articulated succession framework has, in numerous instances, resulted in intra-family disputes, voting fragmentation, deadlocks within governing bodies, operational paralysis, and destabilisation of clinical departments. Many hospitals derive their institutional credibility from the professional standing of a specific promoter or clinician and when such individuals exit without an orderly transition plan, the institution can experience immediate vulnerabilities in culture and clinical quality. Even short phases of leadership voids or instability can adversely affect staff retention and patient confidence, consequences from which recovery is often slow and uncertain.

A legally sound succession framework for healthcare organisations must integrate three interdependent pillars: ownership, management, and regulation. Ownership succession concerns the lawful transfer and consolidation of control and economic rights and must be structured to avoid fragmentation, deadlocks or conflicting rights across heirs. Management succession determines who is empowered to direct clinical standards, financial decisions, organisational ethics, and day-to-day operations. This ensures continuity of executive and medical decision-making. Regulatory succession addresses the continuity of statutory licences, approvals, compliances and mandated committees, many of which are tied to specific premises, named individuals or formally designated authorities. Effective succession planning necessitates harmonising these domains.

Generic succession plans frequently fail in healthcare settings because they do not reflect the operational realities or regulatory sensitivities of the sector. Healthcare institutions cannot rely on template structures, non-binding family arrangements or presumptions of a harmonious transition. A Will is likely insufficient to prevent governance paralysis, unintended dilution of control, or protect against regulatory disruptions.



Experience across the sector demonstrates that untailored documentation is vulnerable to litigation, competing interpretations, and interpersonal conflict. Accordingly, healthcare organisations increasingly require bespoke, scenario-tested legal structures that can be activated immediately upon a triggering event and that continue to function reliably during periods of uncertainty.

Passing the Torch – Private Businesses

For promoter-led hospitals, private trusts and holding entities have proven to be effective succession vehicles. A private trust permits consolidation of ownership, continuity of voting control, and insulation of the operating entity from fragmentation. Through a trust, a founder can specify the distribution of control rights and economic benefits, delineate voting protocols, allocate leadership roles under various succession events, and build mechanisms for dispute management that preserve institutional continuity.

Unlike default inheritance laws, which may create fragmented shareholding or involuntary co-management among heirs, trust deeds are drafted with attention to all detail: trustee composition, protector oversight powers, reserved matters, deadlock-breaking mechanisms, incapacity triggers, and substitution provisions must be engineered to dovetail with statutory requirements under the Indian Trusts Act, and the various corporate and securities laws, and the regulatory regime applicable to clinical establishments. When combined with holding companies or layered operating structures, they provide additional protection from shareholder disputes, regulatory exposure, and divergent interests within the next generation.



Crucially, the trust deed must be aligned with the articles of association and any shareholders' agreement of the operating entities. Any inconsistency between these documents risks rendering parts of the trust structure ineffective, especially in relation to voting covenants, transfer restrictions, pre-emptive rights, tag-along or drag-along clauses, and reserved matters requiring supermajority board or shareholder approvals. For listed companies, SEBI imposes an affirmative obligation on the board and Nomination and Remuneration Committee to ensure that plans are in place for orderly succession at both the board and senior-management level.

Legal infrastructure alone, however, does not guarantee continuity. Healthcare institutions also rely on an internal value system encompassing clinical ethics, patient-first protocols, teaching missions, philanthropic objectives, and founder-driven culture. This value system must be deliberately preserved. As organisations evolve into multi-generational entities, differences in professional training,

expectations and strategic priorities can create disconnects.

In such contexts, supplementary governance instruments – family constitutions, letters of intent, legacy statements, next-generation qualification frameworks and structured induction pathways – bring clarity regarding eligibility for leadership, behavioural expectations, and governance norms. Although not strictly legal documents, these frameworks reduce ambiguity, mitigate intra-family friction, and support cohesion during periods requiring decisive governance.

Public Legacy and Charitable Hospitals

Many mission-driven hospitals are held within public charitable trusts, registered societies or Section 8 companies. Public trusts across states are subject to state-level statutes such as the Maharashtra Public Trusts Act, the Tamil Nadu and Gujarat public trust codes, and the central regime governing charitable property. A common statutory theme is the supervisory authority's power to intervene, modify or enforce schemes for the proper administration of the objects of the venture.

In some cases, promoters prefer the corporate-governance rigour of a Section 8 company, which offers predictable board processes, director rotations, committee structures and statutory audit trails. Where a public trust owns a Section 8 operating company, the Articles of Association and shareholders' agreements must be synchronised with the trust deed or scheme to prevent doctrinal conflicts between trust law and company law, particularly in relation to appointment rights, reserved matters and charitable-purpose compliance.

Additionally, as many charitable hospitals receive tax-exempt income, or donor-directed grants, continuity of registrations under Sections 12AB and 80G of the Income Tax Act 1961 must be preserved through trustee transitions. The IncomeTax Department imposes strict timelines for reporting changes in trustees, principal officers and key functionaries; delays can result in suspension of exemption and donor uncertainty. Where foreign contributions are received, the Foreign Contribution (Regulation) Framework requires immediate updating of office-bearer details, authorised signatories and designated bank accounts, making governance stability critical.

Where the charitable hospital is not part of the promoter family's primary business operations but has been established as a philanthropic initiative—frequently bearing the family name—the legal, fiduciary and reputational implications of weak governance are often underestimated. The attachment of a personal or family name creates an enduring association with the institution's conduct. Compliance failures, financial irregularities or governance lapses can rapidly escalate into proceedings before the Charity Commissioner, taxation authorities, or regulatory agencies, and can attract adverse media reporting. Even absent wrongdoing by the family, deficiencies in trustee oversight or control systems may result in regulatory scrutiny and reputational damage.

The above mandate that succession must be documented with clarity from inception to avoid converting a philanthropic initiative into a long-term liability. Provisions on the trustee appointment and retirement processes, emergency succession protocols for death or incapacity, quorum and voting thresholds, conflict-of-interest rules for related-party transactions, term li its for family trustees,

delegation to Chief Executive Officers or Medical Directors, check and balance requirements and precise boundaries between strategic trustee oversight and operational management are must haves.

Succession Planning in the 'License Raj'

Succession planning must also integrate the extensive regulatory licensing environment applicable to hospitals. Healthcare establishments are subject to a range of approvals, including biomedical waste management permissions, fire safety clearances, radiation safety and AERB approvals, blood bank licences, transplant authorisation requirements, clinical establishment registrations and NABH accreditation. Many of these licences are linked to specific individuals, committees or responsible officers. Leadership changes can trigger mandatory intimation requirements, reconstitution of statutory bodies, or fresh approvals. Failure to anticipate these requirements can inadvertently place the institution out of compliance or restrict operations. A succession plan must therefore incorporate a detailed regulatory mapping exercise so that transitions do not interrupt critical clinical services or compromise safety or statutory compliance.

Ultimately, succession planning for healthcare organisations is not limited to wealth preservation or avoidance of intra-family dispute; it is a governance, compliance and public-interest function. Healthcare founders exercise responsibilities that extend beyond the lifespan of any individual and directly affect patient welfare and community trust. By adopting well-designed legal structures, embedding robust governance frameworks, articulating cultural and operational expectations, and aligning regulatory contingencies, institutions can ensure continuity of mission and service. An effective healthcare succession plan is therefore both a private governance instrument and a public assurance of uninterrupted, safe and compliant healthcare delivery.



REGULATORY **FRAMEWORK**





05

Competition Law is now Central to Healthcare Business Models

Anisha Chand

Competition law is no longer a peripheral compliance issue in India's healthcare sector. It is increasingly shaping how hospitals, diagnostics chains, pharmaceutical companies, and medical device suppliers structure their commercial arrangements. The Competition Commission of India (CCI) is examining market practices across the healthcare and life sciences value chain, with a focus on how different stakeholders interact and where market power may be concentrated or leveraged.

Practices that limit patient choice, restrict ac-

cess for competitors, or rely on information asymmetries are more likely to attract scrutiny. This extends across the supply chain, from manufacturers and distributors to hospitals and digital platforms.

An additional layer of complexity is emerging with the integration of AI into healthcare delivery and decision-making. AI-driven diagnostics, pricing tools, supply chain optimisation, and patient engagement models have the potential to reshape market structures. As these tools become more embedded, the CCI is likely to examine how they influence competitive dynamics, including risks of self-preferencing, exclusion, or data-driven market power.

For large healthcare providers and life sciences companies, this requires closer attention to how pricing, procurement, partnerships, and technology deployments are designed in practice.

Pricing Practices and Captive Supply Chains

The pricing of consumables and medicines through in-house hospital pharmacies is under active scrutiny. A recent complaint against a large hospital chain alleged inflated pricing of essential items, coupled with restrictions on patients sourcing these products externally.

The CCI's decision to expand the scope of the investigation beyond a single hospital is significant. It suggests a concern that such practices may be widespread. The direction of scrutiny is clear. Hospitals should be in a position to justify internal pricing, avoid restrictive sourcing conditions, and ensure a reasonable degree of transparency in procurement and mark-ups. Captive supply arrangements are not inherently problematic, but they will be examined closely where they appear to limit patient choice or impose unjustified costs.

After-Markets and Diagnostic Equipment

The diagnostics segment has highlighted issues in after-markets for high-end medical equipment. In one matter, it was alleged that an OEM restricted access to servicing tools and spare parts, limiting the ability of independent service providers to compete. The CCI declined to investigate further, noting the absence of clear dominance and foreclosure. Even so, the case is instructive. The CCI is unlikely to intervene without evidence of both market power and competitive harm.

That threshold was met in a separate matter involving a supplier of specialised MRI technology. The CCI defined a narrow product market and found the supplier to be dominant within it. Conduct such as withholding essential components and supplying outdated equipment was treated as abusive.

Two points are of importance here.

- Market definition in healthcare can be narrow, particularly for specialised technologies.
- Dominance may arise in niche segments even where overall market presence appears limited

OEMs and diagnostics providers should factor this into how they structure service and supply arrangements.

Exclusivity and Access to Patients

Exclusivity arrangements between hospitals and service providers continue to attract attention. In the case involving a hospital and a stem-cell banking provider, exclusive access to patients was found to potentially restrict competition and reduce patient choice.

The underlying concern is straightforward. Hospitals act as gatekeepers at critical decision points. Where patients rely on hospital guidance, exclusivity can have the effect of foreclosing competing providers. This does not mean all exclusivity is problematic. However, arrangements are more likely to be questioned where they limit patient awareness of alternatives or effectively block competing providers from meaningful access.

Structural Issues and Digital Health

CCI market studies continue to point to structural features that heighten competition risk. These include referral dynamics between doctors and hospitals, tying of products and services, and limited transparency in margins across pharmaceutical and device supply chains. Procurement practices, particularly in high-value equipment, are also under scrutiny where tender conditions appear unduly restrictive.

Digital health is likely to be the next area of focus. Telemedicine platforms, diagnostic aggregators, and e-pharmacies introduce new risks linked to platform control and data use. Issues such as self-preferencing, exclusivity, and data-driven steering of patients are already on the regulator's radar.



Conclusion

The CCI's recent approach reflects a more structured and intervention-ready stance across pharmaceutical, healthcare, and life sciences markets. Its focus is increasingly on how practices across the supply chain interact to shape access, pricing, and competitive conditions. The integration of AI into healthcare business models is likely to intensify this scrutiny. As firms deploy AI in diagnostics, pricing, patient engagement, and supply chain management, questions will arise around data advantages, algorithmic decision-making, and the potential for subtle forms of exclusion or coordination. These are areas the CCI can be expected to examine closely.

For healthcare enterprises, the implication is clear. Competition law considerations need to be embedded at the point where commercial and technology strategies are developed. Pricing structures, supply arrangements, exclusivity clauses, and AI-enabled tools should all be assessed through a competition lens. Organisations that take a proactive approach will be better positioned to manage regulatory risk and adapt to a landscape where oversight is expanding in both scope and depth.



06

Environmental Regulation and Compliance Risks in the Healthcare Sector

Jyoti Sinha

Healthcare institutions occupy a unique position within India's environmental regulatory framework. While essential to public health, healthcare operations generate significant environmental impacts, including biomedical waste, chemical effluents, air emissions, radioactive waste and large volumes of plastic and electronic waste.

Environmental enforcement in the healthcare sector has intensified considerably in recent years, with increased scrutiny from the Central Pollution Control Board (CPCB), State Pollution Control Boards (SPCBs), the National Green Tribunal (NGT) and High Courts.

For healthcare companies, environmental compliance is therefore both a regulatory requirement and a key operational risk area.

Core Environmental Laws Applicable to Healthcare Facilities

Healthcare establishments are subject to India's primary environmental statutes irrespective of ownership structure or scale.

Environment (Protection) Act 1986

The Environment (Protection) Act 1986 is the umbrella legislation governing environmental protection in India and forms the basis for rules regulating biomedical waste, hazardous waste, plastic waste and e-waste. Healthcare and pharmaceutical facilities must comply with prescribed standards relating to air emissions, wastewater discharge and waste management. Non-compliance may result in closure directions, environmental compensation and criminal prosecution. Pharmaceutical manufacturing units are additionally subject to sector-specific discharge and emission standards regulating pollutants such as chemical oxygen demand, antibiotic residues and solvent emissions.

Air (Prevention and Control of Pollution) Act 1981

Hospitals and healthcare facilities operating emission-generating equipment — including diesel generators, boilers, incinerators and sterilisation units — must obtain statutory approvals from the SPCBs. These approvals typically include Consent to Establish (prior to installation) and Consent to Operate (prior to commencement of operations). Large healthcare facilities may also be required to install continuous emission monitoring systems.

Water (Prevention and Control of Pollution) Act 1974

Hospitals, laboratories and diagnostic centres generating wastewater must obtain regulatory consents for the discharge of sewage and trade effluents. Healthcare facilities are typically required to install and operate Sewage Treatment Plants (STP) and Effluent Treatment Plants (ETP). These systems are designed to treat wastewater containing pathogens, chemical reagents, disinfectants and biological contaminants generated during healthcare operations.

Atomic Energy Act 1962

Healthcare institutions using diagnostic and therapeutic radiation equipment — such as CT scanners, PET-CT units, nuclear medicine systems and radiotherapy equipment — must obtain approvals from the Atomic Energy Regulatory Board (AERB) and comply with radiation safety and disposal protocols.



Biomedical Waste and Other Waste Management Obligations

Healthcare facilities generate multiple categories of regulated waste. The key compliance frameworks include:

Biomedical Waste Management Rules 2016

These constitute the core regulatory regime governing healthcare waste in India. They apply to hospitals, clinics, laboratories, blood banks, veterinary facilities and diagnostic centres. Key compliance obligations include segregation of biomedical waste at source, colour-coded waste disposal systems, barcode-based tracking of waste movement, authorisation from Pollution Control Boards, staff training and record-keeping requirements. Non-compliance may lead to prosecution, environmental compensation and closure orders.

Hazardous Waste Rules 2016

Pharmaceutical facilities, laboratories and diagnostic units generating hazardous materials — including expired drugs, solvents and chemical residues — must ensure storage, tracking and disposal through authorised Treatment, Storage and Disposal Facilities.

E-Waste Management Rules 2022

Healthcare institutions are typically classified as bulk consumers of electronic equipment, including diagnostic machines and laboratory instruments. Discarded equipment must be disposed of through authorised recyclers, with mandatory documentation and compliance reporting.

Plastic Waste and Solid Waste Rules

Hospitals generate substantial quantities of plastic waste through syringes, tubing, IV bags and sterile packaging. Facilities must ensure proper segregation and disposal through authorised recyclers. Non-biomedical municipal waste generated from hospital operations is governed by the Solid Waste Management Rules 2026 and the Plastic Waste Management (Amendment) Rules 2026.

Environmental Approvals for Healthcare Infrastructure

Environmental approvals may be required for the development or expansion of healthcare infrastructure. Under the Environmental Impact Assessment Notification 2006, healthcare projects with a built-up area exceeding 20,000 sq. m. require prior environmental clearance. Typical approval conditions include installation of STPs and ETPs, rainwater harvesting and water recycling systems, green-belt development and environmental management plans.

Healthcare projects may also require additional permissions such as groundwater abstraction approvals, fire-safety clearances and zoning approvals under municipal regulations.

Pollution Control Board Classification of Hospitals

The CPCB categorises industries based on pollution potential under the Red-Orange-Green-White classification system. Large

hospitals are typically classified as Red category establishments due to high wastewater generation, operation theatres and laboratories, sterilisation activities, incineration operations. This classification subjects hospitals to heightened regulatory monitoring and compliance requirements.

Emerging Sustainability Expectations

Environmental compliance is increasingly linked with performance from a sustainability point of view and investor expectations in the healthcare sector. Large healthcare providers are adopting sustainability initiatives such as renewable energy integration, water neutrality strategies, sustainable hospital infrastructure, environmental reporting frameworks. Many institutions are aligning with international standards such as Global Reporting Initiative (GRI) sustainability reporting frameworks and NABH sustainability guidelines.

Increasing Environmental Litigation in the Healthcare Sector

Environmental disputes involving healthcare institutions are becoming increasingly common. Regulatory and litigation risks frequently arise in relation to improper biomedical waste disposal, violations of pollution control board consents, hospital construction without environmental clearance, groundwater extraction violations, non-compliance with radiation safety requirements. Indian courts and the NGT have consistently held that improper biomedical waste management directly affects public health and the constitutional right to a clean environment.





07

Tax Hotspots in the Healthcare Sector

Vinita Krishnan
Viraj Doshi

The Indian healthcare industry has witnessed rapid growth across medical devices, hospitals, diagnostics and health-tech. With increasing foreign participation, investors and healthcare / health-tech companies must carefully evaluate the Indian tax and regulatory framework.

Investment Options

Investments in the healthcare sector may be structured by way of equity, compulsorily convertible instruments or debt, and the choice of instrument should be evaluated from both regulatory and Indian income-tax perspectives. Equity funding is generally preferred for

long-term investments, though dividends are not deductible in India and are taxable in the hands of the

- Resident investors (at the applicable ordinary rates)
- Non-resident investors (at the rate of 20%, subject to treaty relief),

while exit by way of transfer of shares may trigger Indian capital gains tax at the rate of

- 12.5% for long term capital assets (excluding unlisted bonds/debentures, etc.)
- The applicable ordinary tax rates for short term capital assets and unlisted bonds/ debentures (subject to tax treaty relief).

Debt funding, including shareholder loans or debentures, may offer cash extraction through interest, but interest payments may be subject to withholding tax in India at the rate of

- 10% on domestic interest payments
- 20% (in case of debt raised from a non-resident in foreign currency, subject to tax treaty relief)
- Applicable ordinary tax rates (in case of debt raised from a non-resident in Indian currency, subject to tax treaty relief)
- Concessional/nil rates in case of debt raised from a non-resident in GIFT/by GIFT, and deductibility in the hands of the Indian borrower may be restricted by transfer pricing, thin capitalization provisions and related anti-avoidance rules.

Hybrid or convertible instruments also require careful review, as their characterisation as debt or equity may differ across tax, company law and foreign exchange frameworks, which in turn may affect withholding, deductibility and exit treatment. Further, tax valuation is a key consideration for any structure, particularly where shares or convertible instruments are transferred or where healthcare valuations are driven by intangibles such as platform technology, regulatory approvals, clinical data, brand value or product pipeline. Accordingly, robust valuation documentation should be maintained for equity pricing, conversion mechanics and intra-group debt terms, including interest rates from an Indian tax, transfer pricing and foreign exchange standpoint. Overall, the optimal structure should be determined after considering withholding leakage, deductibility, valuation considerations, treaty access (for non-resident investors), regulatory permissibility, General Anti-Avoidance Rules (GAAR) implications and the intended repatriation and exit pathway.

Technical Collaboration

Further, in the event of any technical collaboration for establishment of healthtech models, including through joint ventures, often involves the transfer or licensing of intellectual property (IP). In such cases, the taxability of any transfer of IP requires careful evaluation. Key factors would include the situs of the IP and the extent of its nexus with India (for non-resident investors), as these are relevant to determining whether any capital gains or royalty tax exposure arises in India. For residents as well as non-residents, capital gains are taxable at the rate of 12.5% (where the IP was held for a period exceeding 24 months); or else at the applicable ordinary rates. Royalty income is taxable at the applicable ordinary rates for residents whereas

at the rate of 20% for non-residents (subject to treaty relief). The residence of the IP owner, together with the jurisdictions in which the IP is registered, held and commercially exploited, are also important considerations in assessing the Indian tax implications of the proposed arrangement.

Dealmaking

Transactions in the healthcare sector must be structured with care, given India's stringent withholding tax regime, under which the payer is required to withhold taxes on sums chargeable to tax in India. Non-compliance can result in recovery of tax, interest, and penalties from the payer, and may also result in disallowance of the expenditure in the hands of the payer. Investors should therefore evaluate the seller's tax position (particularly in case of non-residents), ensure requisite compliances, and consider contractual protections such as indemnities or tax insurance.

Further, the tax treatment of deferred or earnout payments depends on how such payments are structured and triggered and should be examined closely to avoid timing or characterization issues. Buyers should also be mindful of potential successor liability for the seller's unpaid taxes(especially in case of business acquisitions) and assess whether a tax clearance certificate(in share/business/asset acquisitions) or other safeguards are necessary. Overall, prudent tax diligence and appropriate contractual protections are key to mitigating exposure in healthcare M&A transactions.

While undertaking transactions in the healthcare space, the following key Indian income-tax issues / aspects ought to be suitably considered:

Freebies to Healthcare Professionals

Expenses incurred on providing freebies, gifts, or other benefits to medical practitioners, which are prohibited by the regulatory medical framework, are disallowed as business deductions. This restriction is particularly relevant for medical device and health-tech companies promoting products in India. Any non-compliance risks not only disallowance but also potential repercussions for the companies as well as the medical practitioners under medical regulatory frameworks. The freebies, gifts or other benefits received by medical practitioners are considered taxable income in the hands of medical practitioners and may entail withholding tax obligations for the payors.

Consultancy Arrangements Vs Employment

Healthcare entities often engage Indian resident doctors or specialists either as consultants or employees. The characterisation is critical for withholding tax purposes for the healthcare entities:



Employment

Salary taxation in India (with employer withholding tax as per applicable slab rates) and social security implications.



Consultancy

Fees subject to withholding tax at 10%.

Tax authorities often undertake a threadbare scrutiny of the consultancy contracts with such doctors to ascertain whether the arrangement is actually an employment relationship. The nature of engagement with the Indian healthcare

entities impacts the taxation of such medical practitioners. Accordingly, careful drafting of agreements is vital.

Charity and Exemptions to Hospitals

Hospitals and charitable trusts engaged in healthcare may claim tax exemptions from Indian income-taxes, provided the specified conditions are met with respect to application of their income for specified purposes, restriction on commercial receipts, registration and audit requirements. Hence, acquisitions of charitable hospitals merit a careful diligence to ensure compliance with these exemption conditions, as any violations could trigger taxability.

Transfer pricing

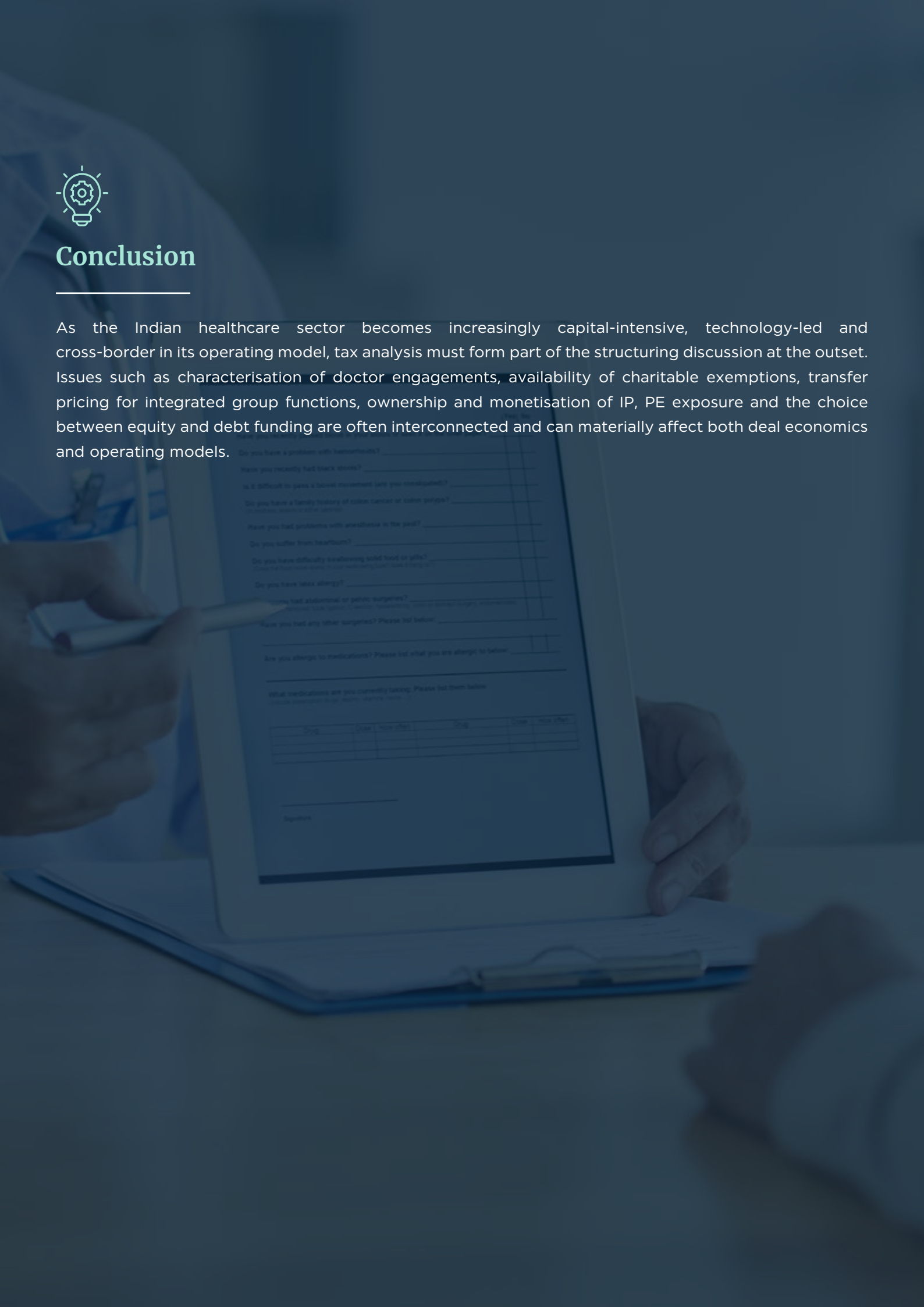
Intra-group service arrangements (clinical trials, research and development support, contract manufacturing, distribution, etc.) are quite the norm in multinational healthcare groups. All such transactions must meet the arm's length standard, supported by robust benchmarking and documentation.

Further, secondary adjustment provisions under Indian tax law require that any transfer pricing adjustments resulting in additional taxable income in India be repatriated from the overseas affiliate to the Indian entity within the prescribed time. If the amount is not brought back within the prescribed time, it is treated as an advance to the foreign affiliate and notional interest may be taxed in India at the applicable rates.

Permanent Establishment

The risk of any foreign entity creating a taxable presence / permanent establishment ("PE") in India should be carefully evaluated. Where the foreign entity forms a taxable presence / PE in India, the profits of the foreign entity attributable to the PE are taxable at 35% (plus surcharge and cess). Several instances where ascertaining this risk is important are as under:

- Secondment of medical practitioners from foreign entities to Indian hospitals
- Medical equipment or facilities installed in Indian hospitals which remain under the control or disposal of the foreign supplier
- Control exercised by the licensor over the licensee under an IP licensing transaction
- Marketing and distribution activities undertaken by an Indian group company of the foreign entity



Conclusion

As the Indian healthcare sector becomes increasingly capital-intensive, technology-led and cross-border in its operating model, tax analysis must form part of the structuring discussion at the outset. Issues such as characterisation of doctor engagements, availability of charitable exemptions, transfer pricing for integrated group functions, ownership and monetisation of IP, PE exposure and the choice between equity and debt funding are often interconnected and can materially affect both deal economics and operating models.



08

Tax and Regulatory Landscape for the Healthcare Industry

Dinesh Agrawal
Pranay Sahay

The healthcare sector comprises a broad economic ecosystem engaged in the provision of medical products and services for health maintenance, prevention, diagnosis, treatment and rehabilitation. It includes hospitals, clinics, medical device suppliers, insurers, diagnostic laboratories, research organisations, clinical trial entities, outsourcing providers and telemedicine platforms. Healthcare is one of the largest sectors in India, both in terms of revenue and employment, and has witnessed sustained growth due to expanding access, improving service delivery and increasing expenditure by both public and private participants.

From an indirect tax perspective, the principal levies relevant to the sector are: GST, which applies to the supply of goods or services or both as well as import of services; and Customs Duty, which applies to the import of goods into India.

GST

GST in India operates through a dual model at the Central and State levels. The principal statutes governing GST are set out below.

Legislation	Government	Scope of Levy
Central Goods and Services Tax Act 2017 (CGST Act)	Central Government	Provides for concurrent levy and collection of 'CGST' and 'SGST' on 'intra-state supply' of goods or services or both.
State Goods and Services Tax Acts (SGST Act)	State Government	
Integrated Goods and Services Tax Act 2017 (IGST Act)	Central Government	Provides for levy and collection of 'IGST' on 'inter-state supply' and import of goods or services or both.

GST is a destination-based consumption tax levied on the 'supply' of goods or services or both, made for a consideration by a person in the course or furtherance of business. The term 'supply' is defined broadly to include all forms of supply of goods or services or both, such as sale, transfer and disposal etc, made or agreed to be made for a consideration in the course or furtherance of business.

The healthcare sector falls within the ambit of 'business', which includes commerce, profession and vocation. Under the GST framework, movable property is generally treated as 'goods', while anything other than goods is treated as a 'service'. Where goods and/or services are supplied together for a single consideration, the supply may be characterised as a 'composite supply' or a 'mixed supply', with differing tax consequences.

Taxation of Healthcare Services

'Healthcare services' has been defined to include services by way of diagnosis, treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicine in India, as well as transportation of a patient to and from a clinical establishment. However, the definition excludes hair transplant and cosmetic or plastic surgery, except where such procedures are undertaken to restore or reconstruct anatomy or bodily functions affected by congenital defects, developmental abnormalities, injury or trauma.

Exempt Services

- 'Healthcare services' provided by a 'clinical establishment', an 'authorised medical practitioner' or 'paramedics'
- Services provided by a veterinary clinic in relation to the health care of animals or birds
- Services provided by way of transportation of a patient in an ambulance

Taxable Services

- Cosmetic or plastic surgery other than undertaken to restore or reconstruct anatomy or bodily functions affected by congenital defects, developmental abnormalities, injury or trauma
- Room charges exceeding INR 5000 per day other than other than Intensive Care Unit, Critical Care Unit, Intensive Cardiac Care Unit, or Neo natal Intensive Care Unit.

The CGST Act is the nodal legislation governing implementation, tax payment, and the like in the GST era. The provisions of the CGST Act are identical to the relevant SGST Act. Hence, any reference in this document to statutory provisions of the CGST Act should also be read as being equally applicable to the SGST Act.

'Clinical Establishment', 'Authorised Medical Practitioner' and 'Paramedics'

'Clinical establishment' includes hospital, nursing home, clinic, sanatorium offering services or facilities requiring diagnosis or treatment or care for illness, injury, deformity, abnormality or pregnancy in any recognised system of medicines in India. Such clinical establishments are required to be registered under the provisions of the Clinical Establishments (Registration and Regulation) Act 2010.

'Authorised medical practitioner' includes a medical practitioner having requisite qualification to practice in any recognised system of medicines in India. Indian System of Medicine such as Ashtang Ayurveda, Unani, Siddha and Sowa-Rigpa Systems of Medicine. Qualified medical practitioners are required to be enrolled in the State Register or the National Register to practice medicine as provided under the National Medical Commission Act 2019.

Paramedics are highly trained emergency medical professionals who provide advanced life-saving care, stabilise patients, and transport them to hospitals. Presently, there is no Act or Council to regulate the functioning of paramedics.

'Composite Supply' and 'Mixed Supply'

GST law recognises the concepts of 'composite supply' and 'mixed supply'. A composite supply arises where two or more taxable supplies of goods or services or both are naturally bundled and supplied in conjunction with each other in the ordinary course of business, one of which constitutes the principal supply.

In-patient

In-patient treatment ordinarily involves the provision of medical services together with medicines, implants, consumables, food and nursing support. Where such elements are supplied in the course of treatment to an in-patient and are naturally bundled with the principal supply of health care services, the entire supply would qualify as a composite supply, with the principal supply being the health care service. On that basis, bed, medicines and consumables supplied as part of in-patient treatment would also be treated as exempt.

Out-patient

By contrast, in case of out-patient treatment, medicines or other products sold separately over the counter through a hospital pharmacy and therefore, would not ordinarily qualify as part of such composite supply and would be liable to GST at the applicable rate.

Areas of Dispute

Room charge under composite supply: As room charges exceeding INR 5000 per day are taxable, question would arise as to whether such room charges forming part of the composite service could be split and considered as a separate taxable supply rather than part of the exempt composite package.

Orthodontics treatment: Dental alignment, or orthodontics, corrects crooked, crowded, or misaligned teeth and jaw issues to improve both

oral health and aesthetics. The dispute arises as to whether such treatment is 'exempt healthcare service' or 'taxable cosmetic service'.

Supply of medicine and other medical devices: Many hospitals offer package services for in-patient treatment without giving any breakup of medicine or devices used. In case of non-package service, hospitals provide detailed item-wise breakup of medicine or devices used in the treatment. Disputes arise where breakup is provided in the invoice although same is part of the composite service.

Wellness services: Services provided in the nature of general wellness, spa offerings or non-medical screening may fall outside the exemption, even if described using AYUSH terminology. The availability of the exemption is therefore fact-specific and depends on the nature of the service, the qualifications of the practitioner and the recognised scope of practice.

Diagnostic Services

Services provided by diagnostic laboratories are generally treated as 'healthcare services' and are exempt from GST. The statutory definitions of 'healthcare services' and 'clinical establishment' expressly extend to entities engaged in diagnostic or investigative services in relation to disease. Accordingly, pathological testing, blood testing, imaging and similar diagnostic investigations undertaken for medical purposes would ordinarily qualify for exemption. The exemption does not depend on whether the service is delivered through a physical facility or through a technology-enabled model such as home sample collection with digital reporting. What is relevant is the nature of the underlying supply.

Where an online platform merely facilitates the booking of diagnostic services and charges a separate facilitation, technology or platform fee, the laboratory's diagnostic service may remain exempt, while the platform fee may constitute an independent taxable supply liable to GST at 18%. Similarly, the sale of test kits or other goods as separate supplies would be taxable at the applicable rate.

Medicines and Medical Devices

The supply of medicines, pharmaceutical formulations, medical devices and consumables is generally taxable under GST unless specifically exempted or subject to a concessional rate. The applicable rate depends on product classification, including the relevant tariff heading, description and rate notification. As a general principle, medicines and medical devices supplied independently are taxable as goods at the applicable rate. However, where medicines, implants or consumables are supplied as part of a composite in-patient health care service, the tax treatment may follow that of the principal exempt supply, subject to the facts of the arrangement.



Health Insurance and Life Insurance

The taxation of insurance products under GST has been the subject of ongoing policy discussion. Certain materials refer to recommendations or proposals concerning the GST treatment of individual health insurance and individual life insurance products, including the possibility of exemption or rate rationalisation. Since such matters are dependent on formal GST Council recommendations and implementing notifications, the applicable position should be verified with reference to the law in force at the relevant time.

As a general proposition, unless specifically exempted, insurance services remain taxable under GST at the applicable rate. Any distinction between individual and group policies, including employer-sponsored arrangements, should be analysed on the basis of the prevailing statutory framework and notifications.

Telemedicine Services

Telemedicine refers to the delivery of medical consultation, diagnosis and treatment through digital means, including video consultations, mobile applications and online platforms. Where telemedicine services are rendered by a clinical establishment or an authorised medical practitioner and are in the nature of diagnosis, treatment or care, such services should generally qualify as exempt health care services not withstanding the absence of a physical consultation. The mode of delivery does not, by itself, alter the character of the medical service.

However, medicines supplied pursuant to such consultation would be taxable separately as goods at the applicable rate, unless they form part of an exempt composite supply in an in-patient setting. Further, where a digital platform merely provides technological infrastructure, appointment scheduling, payment collection or similar facilitation services in return for a commission or service fee, such platform services would generally constitute independent taxable supplies liable to GST at 18%.

Human Health and Social Care Services

The GST exemption is narrowly framed and applies only to qualifying 'healthcare services' provided by a clinical establishment, an authorised medical practitioner or paramedics. A broader suite of support services, such as regular medical monitoring, assistance during hospitalisation, nursing coordination, medicine delivery, companionship and day-to-day logistical support, may not necessarily qualify for exemption merely because they are health related.

Where such services are supplied by an entity that is not itself a clinical establishment or an authorised medical practitioner, or where the offering extends beyond diagnosis or treatment into social care, assisted living or logistical support, the exemption may not apply.

Customs Duty

Customs Duty in India is a statutory levy imposed on goods imported into, or exported from, India under the Customs Act 1962 (Customs Act). Section 12 of the Customs Act authorises the levy and collection of Customs Duty on imported goods at the point of importation, that is, when the goods cross the customs frontiers of India. The Customs Act sets out the legal

framework for assessment, valuation, clearance and enforcement, while duty rates are prescribed under the Customs Tariff Act 1975 (CTA).

The CTA prescribes duty rates for goods classified according to the Harmonised System of Nomenclature (HSN), thereby aligning Indian tariff classification with international standards. Each imported product must be classified under the relevant HSN heading and sub-heading, and the applicable duty rate follows from that classification.

In addition to Basic Customs Duty, imports may also be subject to other levies, such as Social Welfare Surcharge and other applicable cesses. The effective duty incidence may further be modified by exemption notifications issued under Section 25 of the Customs Act, which may grant full or partial, conditional or unconditional exemptions depending on the nature of the goods, the end use, the class of importer or other specified criteria.

In the case of medical equipment, it is also necessary to verify whether the relevant product is subject to mandatory certification by the Bureau of Indian Standards (BIS). Certain electronic medical devices, such as digital thermometers, blood pressure monitors, nebulisers and pulse oximeters, may fall within the BIS Compulsory Registration Scheme or be covered by applicable Quality Control Orders. Where BIS compliance is mandatory, registration must be obtained prior to import. Certification is granted on the basis of testing in a BIS-recognised laboratory in India, and the product must bear the prescribed BIS Standard Mark and registration number. Customs authorities may verify BIS compliance at the time of import, and consignments lacking the required registration may be detained.



Conclusion

The GST and Customs Duty framework applicable to the healthcare sector is layered, fact-specific and continues to evolve through legislative amendments, GST Council recommendations and judicial pronouncements. While core health care services provided by qualifying entities benefit from exemption, the boundaries of that exemption are frequently contested whether in relation to room charges, composite supplies, orthodontic treatment, wellness services or technology-enabled delivery models.

Similarly, the taxability of medicines, medical devices and insurance products requires careful analysis of classification, applicable exemption notifications and the specific arrangements in place. On the Customs Duty side, importers of medical equipment must account not only for applicable duty rates and exemption notifications, but also for regulatory compliance requirements such as BIS certification, which operate independently of the tariff framework. Given the complexity and the pace of change in this area, entities operating in the healthcare sector are likely to benefit from a structured review of supply chain taxes, contractual terms and compliance positions.



09

Evolving Criminal Enforcement in the Healthcare Space: Key Risk and Compliance Strategies

Susanah Naushad

Hospitals, diagnostic centres, clinical establishments, medical device companies and medical technology platforms in India are now operating under close scrutiny from regulators, prosecutors and courts. The sector often receives public benefits in the form of subsidised land and tax relief and participates in government funded insurance schemes. At the same time, it is expected to meet high standards of integrity in the way it treats patients and deals with public money. Recent decisions show that criminal law exposure is no longer confined to a few errant doctors. Hospital managements and boards are increasingly being examined for how

they supervise professionals and fulfil public law obligations.

Public Concessions and Obligations Towards Economically Weaker Sections

In Social Jurist A Lawyers Group v. Government of NCT of Delhi, the Delhi High Court held that private hospitals which received land at concessional rates from the Government of NCT of Delhi were bound by conditions requiring free treatment for patients from economically weaker sections. The Supreme Court subsequently endorsed directions that such hospitals must provide specified proportions of outpatient and in patient services free of cost and recognised that persistent non-compliance could attract serious consequences, including cancellation of leases.

From a criminal law perspective, the same fact pattern can support charges of cheating and criminal breach of trust under the Bharatiya Nyaya Sanhita 2023 (BNS) where hospitals induce the state to part with valuable property on the representation that they will provide free treatment but then systematically fail to do so. Where public officials collude with hospital management in diluting or ignoring concession conditions in exchange for an undue advantage, sections on bribery of public servants and corporate liability under the Prevention of Corruption Act 1988 also become applicable.

Conduct of Individual Doctors and Exposure Under the Prevention of Corruption Act

The conduct of individual doctors is central to the risk profile. The Indian Medical Council Professional Conduct Etiquette and Ethics Regulations 2002, now carried forward under the National Medical Commission, prohibits doctors from accepting gifts, travel facilities, hospitality, cash or monetary grants from the pharmaceutical and allied healthcare industry.

In M S Apex Laboratories Pvt Ltd v. Deputy Commissioner of Income Tax, the Supreme Court refused to allow tax deductions for expenditure on such freebies and held that these payments violated the code of ethics. The Court observed that a prescription can be manipulated by the motive to avail freebies and that the cost of such benefits is passed on to patients. Although the case arose in the context of a pharmaceutical company, the reasoning extends to hospitals, diagnostic centres and medical technology platforms that provide similar benefits to doctors.

Where doctors work in public hospitals or other establishments that qualify as public authorities, they are treated as public servants for the purpose of the Prevention of Corruption Act 1988. A doctor who accepts any gratification other than legal remuneration, in return for prescribing a particular product, or referring a patient to a preferred facility or admitting a patient under a scheme will be liable for bribery. The hospital that offers or tolerates such arrangements can face liability as a commercial organisation that bribes a public servant, and its directors or senior management can be prosecuted if they consented to or were negligent about such conduct.

Prescribing Behaviour, Affordability and Patient Rights

The link between prescribing behaviour and constitutional rights has been highlighted in Vijay Mehta v. State of Rajasthan. The Rajasthan High Court recognised that the right to obtain treatment at affordable prices of medicines is one aspect of the right to life under Article 21 of the Constitution. It stressed the importance of generic prescribing and the duty of the State to ensure that citizens are not priced out of essential medicines. Public interest litigation before the Supreme Court continues to press for strict implementation of generic prescribing norms and refers to the dangers of incentive driven prescriptions that were identified in Apex Laboratories. For hospitals and clinical establishments, this means that patterns such as repeated prescription of high-cost brands without medical justification, combined with evidence of benefits from suppliers, can support allegations of cheating and abetment of corruption. Professional misconduct findings by medical councils can be used by investigators as corroborative evidence of dishonest intent.

Fraud and Mis-billing in Public Health Insurance Schemes

Another major area of risk concerns fraud and mis-billing in public health insurance schemes, including Ayushman Bharat Pradhan Mantri Jan Arogya Yojana (AB PM-JAY) and state schemes. Oversight bodies have reported patterns such as phantom admissions, unnecessary procedures, upcoding to higher packages, unbundling of procedures to maximise reimbursement and creation of fictitious beneficiary records. These practices can attract offences of cheating, criminal breach of trust and forgery under the BNS. Where scheme officials are compromised, the Prevention of Corruption Act 1988 would kick in. If the proceeds of such fraud are layered through complex structures, the Prevention of Money Laundering Act 2002 may also be invoked.

Practical Compliance Steps for Healthcare Entities

Healthcare organisations increasingly want clarity on what concrete measures they should adopt to manage these risks. While the precise approach will vary across institutions, an effective compliance framework should at a minimum incorporate the following core elements to reduce the likelihood of non-compliance.

- Maintain a register of all public concessions and regulatory benefits that the institution enjoys, such as subsidised land or tax exemptions. For each concession, record the linked obligations, including quotas for patients from economically weaker sections, and require periodic board level reporting on compliance.
- Adopt a clear anti bribery and anti-corruption policy that applies to all interactions with doctors and other healthcare professionals. The policy should expressly prohibit referral commissions, success linked payments, gifts and high value hospitality, and should require that all consultancy and speaking engagements are on the basis of written contracts with fair market value rates and documented deliverables.
- Implement a structured doctor-engagement framework, including basic due diligence on key doctors, central committee approval for all engagements, and a single register capturing every payment or benefit provided to them.

- Use data analytics to monitor prescribing and referral patterns. Compliance and internal audit teams should receive periodic reports that highlight outliers, for example, unusually high usage of a particular device, high admission rates for specific procedures or repeated referrals to one diagnostic facility. Outliers should trigger enquiries and, where necessary, formal investigations.
- Strengthen governance around participation in government insurance schemes. Segregate roles so that treating doctors are not involved in coding and claims submission. Establish standard operating procedures for documentation, approval and submission of claims, and monitoring specific red flags such as repeated claims for the same beneficiary or unusually high numbers of very expensive packages.
- Create robust internal reporting and investigation mechanisms. Employees and doctors should have access to confidential channels to raise concerns regarding bribery, referral commissions, overbilling or non-compliance with obligations towards economically weaker sections. There should be a written protocol for how such complaints are assessed, investigated and escalated, including when external counsel or forensic support will be brought in.
- Ensure that individual doctors understand their personal exposure. Training modules should explain that accepting benefits can lead to personal prosecution under the Prevention of Corruption Act 1988 and that their conduct can draw enforcement attention to the institution. At the same time, management should make it clear that the institution will not support or reimburse any illegal payments.



Conclusion

The evolving landscape of criminal enforcement in India's healthcare sector necessitates a proactive and comprehensive compliance strategy from all stakeholders, including hospitals, diagnostic centers, and medical technology platforms. With heightened scrutiny from regulators and legal bodies, healthcare entities must align their operations with stringent ethical standards and legal obligations.

This involves meticulous tracking of public concessions, enforcing anti-bribery policies, and implementing robust internal controls. By fostering transparency and accountability, healthcare organisations can mitigate legal risks and uphold their duty to provide equitable and ethical care to all patients, particularly those from economically weaker sections.

TECHNOLOGY





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AI in Healthcare: Unlocking Value While Navigating Regulatory Risks

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AI is fast becoming core infrastructure across the healthcare ecosystem. For Indian healthcare providers, diagnostics companies, health-tech platforms, and pharmaceutical players, AI presents a tangible opportunity to address long-standing structural challenges, including limited access to specialist care, cost inefficiencies, and variability in clinical outcomes. AI-enabled diagnostic tools, clinical decision-support systems, and predictive analytics are already demonstrating their ability to augment human expertise, optimise resource allocation, and improve patient outcomes. In parallel, AI is reshaping drug discovery and clinical trial design by enabling faster

identification of viable candidates and more efficient trial processes. As adoption accelerates, the focus must shift from proof of concept to responsible, scalable, and commercially sustainable deployment, supported by clear legal and regulatory alignment.

A Fragmented but Fully Applicable Regulatory Landscape

This transition brings legal and regulatory considerations into sharp focus. In India, the regulatory landscape governing AI in healthcare remains fragmented and evolving, with no singular framework directly addressing AI. Instead, organisations must navigate a convergence of data protection law, medical device regulation, clinical trial norms, and ethical guidelines. The Digital Personal Data Protection Act 2023 (DPDP Act) sits at the centre of this ecosystem, imposing obligations around lawful processing, purpose limitation, data minimisation, and transparency. Health data, given its sensitive nature, demands compliance discipline.

At the same time, AI-based diagnostic or therapeutic tools may attract scrutiny under medical device regulations, while AI enabled research and drug development must align with clinical trial and ethics committee requirements. The absence of a unified regime does not reduce regulatory exposure; rather, it requires organisations to take a more considered and structured approach to compliance, drawing on existing fram works across data protection, medical device regulation, and clinical research. With the right legal interpretation and structuring, these overlapping regimes can be navigated effectively, enabling organisations to deploy AI solutions with confidence while remaining compliant.

Health-Tech Platforms: AI as Core Infrastructure and Risk Multiplier

For health-tech companies, AI is often the backbone of their offerings. From symptom checkers and telemedicine triaging engines to personalised health insights, remote monitoring, and wearable integrated analytics, AI is embedded into product architecture. This creates a dual layered risk profile spanning development and deployment. At the development stage, key considerations include sourcing and licensing of training data, adequacy of consent for downstream AI use, and potential intellectual property exposure where third-party datasets or models are leveraged. At the deployment stage, the focus shifts to accuracy of outputs, explainability of recommendations, and user transparency, particularly where patients may rely on AI-driven insights in lieu of medical consultation.

Diagnostics Companies: Efficiency Gains with Heightened Liability Exposure

Diagnostics companies are among the most mature adopters of AI, particularly in radiology, pathology, and imaging workflows. AI models are used to detect anomalies, prioritise cases, and assist clinicians in early diagnosis. While this significantly enhances efficiency and throughput, it also introduces heightened expectations around clinical validation, accuracy thresholds, and auditability. More importantly, reliance on AI-assisted outputs raises important considerations around allocation of responsibility. In the event of an incorrect or missed diagnosis, the allocation of responsibility between the AI developer, the diagnostics provider, and the interpreting clinician can be clearly addressed through

contractual frameworks, clinical protocols, and validation standards, even in the absence of settled jurisprudence.

Hospitals: Managing Clinical Integration and Data Responsibility

Hospitals and healthcare providers are integrating AI across both clinical and administrative functions, from patient triaging and ICU monitoring to treatment recommendations and operational optimisation. This creates a layered compliance and risk environment. On the clinical side, hospitals must ensure that AI systems are used as assistive tools rather than substitutes for medical judgment, with clear protocols preserving clinician oversight. On the operational side, hospitals, as primary custodians of sensitive health data, play a central role in ensuring compliant AI adoption.

This includes implementing robust consent mechanisms, controlling access to patient data, and ensuring that vendor arrangements adequately address data usage, security, and breach response. This includes implementing robust consent mechanisms, controlling access to patient data, and ensuring that vendor arrangements adequately address data usage, security, and breach response. Given the increasing reliance on third-party AI solutions, structured vendor onboarding, due diligence, and audit mechanisms enable hospitals to integrate AI tools while maintaining regulatory compliance and operational control.

Pharmaceutical Sector: AI Across the Product Lifecycle

For pharmaceutical and life sciences companies, AI is transforming the entire product lifecycle. In early-stage research, AI accelerates target identification and molecule discovery. In clinical development, it enables smarter trial design, improved patient stratification, and real-time monitoring. Post-approval, AI supports pharmacovigilance and the generation of real-world evidence. Each of these applications introduces distinct legal considerations. The use of large-scale and often cross-border datasets must be aligned with consent requirements and data transfer restrictions under Indian law.

AI assisted clinical trials must adhere to ethics committee approvals, ensure transparency in algorithmic decision-making, and maintain integrity of trial protocols. Additionally, where AI models are developed collaboratively, such as between sponsors, CROs, and technology providers, it becomes important to clearly define ownership of data, models, and outputs upfront. Well-structured agreements can ensure alignment across stakeholders, minimise ambiguity, and support seamless collaboration across the AI development lifecycle.



Data Governance, Bias, and Consent: The Core Legal Risks

Across all stakeholders, a central legal risk lies in the quality and governance of data used to train AI systems. In India, healthcare data is often fragmented, inconsistently formatted, and not fully representative of the country's demographic diversity. This creates a potential risk of algorithmic bias, potentially resulting in inequitable or inaccurate outcomes. However, with appropriate data curation, validation, and governance frameworks, these risks can be significantly mitigated. Closely linked to this is the issue of consent. Under the DPDP Act, while consent remains the primary basis for personal data processing, the law carves out limited exceptions for use of data in relation to research, archiving, and statistical purposes.

That said, reliance on these exceptions is not unfettered. Such processing must be undertaken subject to appropriate safeguards and, critically, the data should not be used to make decisions, profiles, or inferences that are directed at or impact specific identifiable individuals. Organisations must carefully structure AI training and development or deployment activities to ensure that any reliance on these exemptions remains within permissible bounds while continuing to unlock value from data in a compliant manner.

AI in Clinical Trials

These challenges are further amplified in the context of clinical trials, where AI is increasingly used to optimise recruitment, refine inclusion criteria, and enable adaptive designs. While this enhances efficiency and reduces cost, it also raises important considerations around transparency, fairness, and regulatory compliance. The use of diverse and cross-border datasets is critical to ensuring generalisable outcomes but must be carefully aligned with consent and data transfer requirements. Regulatory scrutiny is likely to focus not only on outcomes but also on the explainability and auditability of AI-driven decisions within trial processes. Organisations that proactively build these elements into trial design are likely to benefit from both operational efficiency and regulatory acceptance.

Contractual Structuring as a Risk Management Tool

In this evolving landscape, embedding legal and compliance considerations into the AI lifecycle is essential. A privacy by design approach must be complemented by robust data governance frameworks, clear consent architectures, and continuous risk assessment. Organisations must also recognise that contractual structuring is no longer a back-end exercise but a primary tool for risk allocation.

Thoughtfully designed contractual frameworks not only mitigate risk but also enable scalable AI deployment by clearly defining roles, responsibilities, and rights across stakeholders. Agreements with AI vendors, data partners, research institutions, and platform collaborators must clearly define data ownership, permitted use, liability, compliance responsibilities, and audit mechanisms. This is particularly critical in complex AI ecosystems involving co-development, licensing, and multi-party data sharing.

Legal Assessment is a Strategic Necessity

As AI becomes embedded across the healthcare value chain, legal assessment can no longer be treated as a downstream compliance check. Every stage of the AI lifecycle, from data collection, model training, validation, deployment, to post-deployment monitoring, engages a different layer of India's fragmented but fully enforceable legal framework. The absence of a single AI statute does not imply regulatory flexibility, rather, it calls for a more nuanced and integrated approach to compliance across existing legal frameworks.

For organisations, this means that AI models must be legally stress-tested as rigorously as they are technically validated. Importantly, these considerations are not barriers to adoption, but enablers of sustainable and scalable AI deployment when addressed early and systematically. Questions around whether training data has been lawfully sourced, whether consent frameworks adequately capture AI use cases, whether outputs meet clinical reliability thresholds, and whether liability is appropriately allocated cannot be answered in isolation or retrospectively. They must be addressed upfront, continuously, and in a manner that is tailored to the specific role an entity plays, whether as a developer, deployer, data custodian or clinical intermediary.

As enforcement under the DPDP Act and sectoral regulations evolves, organisations that have embedded legal strategy into their AI operations will be significantly better positioned to scale confidently and withstand scrutiny.





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The Healthcare Sector and the DPDP Act: Key Considerations ahead of Enforcement

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The healthcare sector is inherently data-intensive, involving the continuous collection and processing of vast volumes of personal data. From patient medical records and diagnostic reports to insurance data, telemedicine interactions, and wellness programmes, healthcare entities routinely handle highly sensitive information. This extends beyond patients to include healthcare professionals, caregivers, and, in certain cases, family members.

With the rapid digitisation of healthcare

delivery, through electronic health records, teleconsultation platforms, AI-driven diagnostics, and integrated health ecosystems, the scale and complexity of such processing has increased significantly. Against this backdrop, the DPDP Act introduces a comprehensive framework governing digital personal data in India. Given the sensitivity and volume of data involved, healthcare entities must proactively align their practices, particularly on the following issues ahead of enforcement of the DPDP Act's core obligations.

Role Bifurcation: Data Fiduciary vs Data Processor

A foundational requirement under the DPDP Act is the correct classification of entities as either Data Fiduciaries (which determine the purpose and means of processing) or Data Processors (which process data on behalf of a fiduciary). In healthcare, this distinction is often blurred.

For instance, hospital ownership may vest with one entity, while operations are managed by another. Both may independently influence how personal data is processed, potentially resulting in each qualifying as a Data Fiduciary. Similarly, third-party technology providers engaged for patient apps or electronic records may begin as Data Processors but transition into Data Fiduciaries if they use data for their own purposes (e.g., analytics or product development).

Given that obligations under the DPDP Act differ significantly based on this classification, particularly on notice, consent, and accountability, clear role allocation is critical. This directly impacts contractual structuring, liability allocation, and compliance obligations.

Data Flows and Documentation in Digital Health Ecosystems

Healthcare delivery increasingly operates through interconnected digital ecosystems involving hospitals, labs, pharmacies, insurers, and technology providers. These systems process personal data of both patients and healthcare professionals across multiple touchpoints.

In such an environment, detailed data flow mapping becomes essential. Entities must clearly identify the types of data processed, the purposes of processing, and the parties involved at each stage. Maintaining such documentation is critical to demonstrating accountability under the DPDP Act and forms the foundation for implementing compliant notice and consent mechanisms and contractual safeguards.

New Business Models and Intra-Group Data Sharing

Healthcare providers frequently run continuous engagement programmes, such as follow-ups, wellness initiatives, targeted alerts, and promotional campaigns, using personal data collected at the initial point of care. This data is also often shared across group entities.

Under the DPDP Act, personal data can only be processed for a lawful purpose for which consent has been obtained (unless another valid ground applies) and requires clear notice of such purposes. Accordingly, it is essential to ensure that downstream uses (including engagement and marketing) are covered within the original consent; and intra-group data sharing is transparently disclosed and, where required, consented to.

Legacy consent frameworks, often broad or bundled, may not meet the DPDP Act's standards of specificity. A review and redesign of consent architecture may therefore be necessary to ensure it is granular and purpose specific.

Clinical Research and Applicability of Exemptions

While the DPDP Act provides an exemption for processing of personal data for research, archiving, or statistical purposes, its applicability requires careful evaluation. The DPDP Act provides that such processing will be exempt where it is necessary for these purposes, provided that the personal data is not used to take any decision specific to a data principal and is carried out in accordance with prescribed standards.

The Digital Personal Data Protection Rules 2025 (DPDP Rules) further clarify that this exemption is available only where the processing complies with the standards set out in the Second Schedule, including requirements relating to lawful processing, purpose limitation, data minimisation, accuracy, storage limitation, and implementation of reasonable security safeguards, along with accountability of the data fiduciary.

Processing of Children's Personal Data

The healthcare sector routinely processes children's data, particularly in paediatric care. Under the DPDP Act, a 'child' is defined as an individual below 18 years of age, and such processing ordinarily requires verifiable consent of a parent or lawful guardian. The DPDP Act also imposes heightened safeguards, including restrictions on processing that may be detrimental to a child's well-being, as well as prohibitions on tracking, behavioural monitoring, or targeted advertising directed at children.

However, the DPDP Rules provide specific carve-outs from these obligations. In particular, the requirements relating to parental consent and restrictions on certain forms of processing do not apply where the processing is undertaken by specified classes of data fiduciaries, or the processing is carried out for specified purposes, in each case subject to prescribed conditions. For instance, clinical establishments, mental health establishments, and healthcare professionals may process children's personal data without triggering these requirements, where such



processing is limited to the provision of healthcare services and is necessary for the protection of the child's health.

Accordingly, the availability of these exemptions is contingent on a combination of the nature of the entity, the specific purpose of processing, and adherence to the prescribed conditions. Healthcare organisations must therefore assess whether they fall within the notified class of data fiduciaries and whether their processing activities are strictly limited to the permitted purposes and conditions. Where these thresholds are not met, entities will be required to implement robust verifiable parental consent mechanisms, supported by appropriate technological and operational controls, to ensure compliance with the enhanced obligations under the DPDP Act.

Conclusion

The DPDP Act marks a significant shift in India's data protection framework, with far-reaching implications for the healthcare sector. The volume and sensitivity of personal data processed, coupled with complex operational models, make compliance particularly nuanced. A proactive review of existing data practices will be critical to identifying gaps and implementing appropriate safeguards. Undertaking this exercise ahead of enforcement will enable healthcare entities to align with legal requirements and evolving regulatory expectations, while maintaining trust in an increasingly data-driven ecosystem.





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Exploring Telemedicine

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Telemedicine is a mode through which healthcare service and medical support can be accessed using communication networks and digital solutions. It serves as a tool for remote diagnosis and treatment. As per the Ministry of Health and Family Welfare (Health Dynamics of India publication for 2022-23), the doctor-to-patient ratio (including AYUSH practitioners, and assuming 80% availability) stood at 1:811 in India. A 2020 study by the World Health Organisation and the Public Health Foundation of India (PHFI) highlighted the imbalance in healthcare professional distribution in India. It noted that while 66% of the population resides in rural areas,

only 33% of health workers are available to deliver services. This disparity in healthcare services available to the public is a point of concern which telemedicine can help address.

The intersection of digital health and Indian law is an evolving landscape that presents both opportunities and challenges for the healthcare sector. With the growing influence of technology on healthcare delivery systems, knowledge of its legal implications is increasingly important. It is essential to explore the legal aspects of digital health in India, including data privacy, telemedicine regulations, and the role of government bodies in shaping this dynamic field.

The Regulatory Regime for Telemedicine in India

Prior to 2020, telemedicine in India was indirectly regulated by the Information Technology Act 2000 (IT Act) and its corresponding rules. The Drugs and Cosmetics Act 1940 (D&C Act) regulates the sale of drugs and prescription requirement for certain drugs. The IT Act and its corresponding rules regulate the protection of sensitive data of patients and the intermediary platforms offering a medium to provide telemedicine . Professional standards relating to matters of privacy and patient confidentiality were also guided by the provisions of the Indian Medical Council Act 1956.

Although there was no express legal framework allowing doctors to provide remote consultations, this ambiguity came into the limelight in the 2018 Bombay High Court case of Deepa Sanjeev Pawaskar v. The State of Maharashtra whereby medication was prescribed by the doctor over the phone after a caesarean surgery, without any in-person consultation. The patient's condition worsened, and she passed away. The Bombay High Court did not actively deal with the legality of telemedicine but, while declining anticipatory bail, observed that a prima facie case of criminal negligence was made out against the doctor. Although the matter was taken up at the Supreme Court, it did not conclusively address the legality of telemedicine, leaving the regulatory position uncertain.

When the COVID-19 pandemic struck in early 2020, it impacted access to in-person consultations. With health concerns throughout the country, hospitals overburdened and fear in the public; the Board of Governors in supersession of the Medical Council of India released the Telemedicine Practice Guidelines (TPG Guidelines) on 25 March 2020 to provide guidance to medical practitioners in realising their full potential in those testing times, and for promoting better healthcare delivery in a safe and effective manner. These guidelines, forming part of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 (MCI Code), provided legal recognition to the practice of telemedicine, whereby any Registered Medical Practitioner (RMP) could consult digitally from any part of India.



In August 2023, the Registered Medical Practitioner (Professional Conduct) Regulations 2023 (NMC Code) were notified, intending to replace the MCI Code (including the TPG Guidelines). The regulation, while borrowing extensively from the TPG Guidelines, aimed to further solidify the provisions pertaining to telemedicine. They included certain guidelines on usage of telemedicine when physical presence is not possible, patient confidentiality and consent. It also changed the restrictions on the categories of drugs which can be prescribed over teleconsultations, allowing more flexibility to RMPs to use their expertise. However, it must be noted that the National Medical Commission has, through a notification dated 23 August 2023, held the NMC Code in abeyance until further Gazette notification. Therefore, the currently active and operative legal standard guide for telemedicine in India continues to be the TPG Guidelines.

Key Elements of the Telemedicine Practice Guidelines 2020

India has actively taken forward the initiative to promote use of telemedicine in India. The eSanjeevani initiative, which started even before the pandemic, is a cloud-based flagship telemedicine technology of the Centre of Development of Advanced Computing (C-DAC) in Mohali, India. It was initially rolled out with the intention to address concerns like lack of doctors and burden of hospitals.

The platform operates with two programmes i.e., 'eSanjeevaniHWC' for health worker-to-health worker teleconsultations, and 'eSanjeevaniOPD' for patient-to-health worker teleconsultations. As of 19 March 2026, eSanjeevani has served more than 457,862,416 patients at over 138,570 Ayushman Arogya Mandirs as spokes through 18,000+ hubs (set up at secondary and tertiary level health facilities and medical colleges etc.) and more than 781 online OPDs serviced by a team of over 231,870 doctors, medical specialists, super-specialists and health workers as telemedicine practitioners. Alongside this, there are multiple private telemedicine platforms available for people to access and use.

The TPG Guidelines, issued in March 2020 by the Board of Governors in supersession of the Medical Council of India (MCI), constitute India's foundational regulatory framework for telemedicine. Incorporated as Appendix 5 to the MCI Code of Ethics, they delineate the legal scope, operational mechanisms, and ethical obligations for remote medical consultation.

Scope and Operational Framework

The TPG authorises RMPs to consult patients through five legally recognised relationships i.e., Patient–RMP, Caregiver–RMP, Health Worker–RMP, RMP–RMP, and Emergency interactions. RMPs must determine if a teleconsultation or in-person examination is clinically appropriate. Communication may occur via video, audio, or text, depending on the case.

Consent and Identification

The TPG mandates informed consent before consultation. Consent may be implied (when a patient initiates the session) or explicit (text, email, or recorded form) if the consultation is initiated by an RMP, caregiver or health worker. Both parties must be clearly identified before proceeding. This safeguard has become essential in a digital ecosystem where India hosts 958 million active internet users, with 57% residing

in rural areas as per the 'Internet in India Report 2025,' jointly prepared by Internet and Mobile Association of India and KANTAR. The availability of connectivity and smartphones has allowed telemedicine to extend beyond cities, bridging gaps in rural healthcare delivery.

Data Privacy, Security, and Platform Obligation

Telemedicine platforms are expected to verify and publicly display the registration number of RMPs; secure data storage and implement reasonable security safeguards, including encryption; offer a grievance-redressal system for patients; and comply with the IT Act and the Sensitive Personal Data or Information (SPDI) Rules 2011. Private telemedicine pla forms are additionally subject to intermediary due-diligence obligations under the Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules 2021. The Digital Personal Data Protection Rules 2025, notified on 13 November 2025 and being brought into force in a phased manner alongside the Digital Personal Data Protection Act 2023, further strengthen patient rights by introducing data-minimisation, purpose-limitation, and consent-based processing principles (including through recognised Consent Managers), together with mandatory personal data breach reporting to the Data Protection Board of India (established by notification dated 14 November 2025) and monetary penalties for non-compliance. The SPDI Rules 2011 continue to apply under the IT Act during the transition, with the DPDP framework progressively taking primacy for personal and health data. Given India's vast digital footprint, these safeguards are critical.

Types and Modes of Teleconsultation

Teleconsultations may be through different modes (audio, video or text), real-time or asynchronous, and may be for the purpose of diagnosis, follow-ups, or a second opinion. As per the Ministry of Health and Family Welfare (MoHFW) Report on Telemedicine or eSanjeevani utilisation, users primarily utilised teleconsultation for initial appointments, with fewer opting for follow-up consultations, however the statistics vary significantly by state. States like Karnataka (62.5%) and Gujarat (24.2%) see higher proportion of follow-up consultations indicating the development in these areas ensuring ongoing patient care and monitoring rather than just initial diagnoses. At the national level, Andhra Pradesh, Tamil Nadu, West Bengal, Karnataka and Uttar Pradesh have led eSanjeevani adoption, together accounting for the bulk of teleconsultations across the country.

Prescriptions and Diagnostic Advice

RMPs are expected to adhere to the same professional standards as in-person care. Prescribing through teleconsultation is governed by the drug lists and conditions set out under various lists of the TPG Guidelines. This is divided into four list i.e., List O (medicines safe to be prescribed over teleconsultation), List A (medicines safe to be prescribed during a video consultation and when being re-prescribed for re-fill in case of a follow up), List B (medicines which can only be prescribed to a follow-up patient who has had an in-person consult for the same condition), and Prohibited List (medicines which cannot be prescribed through the medium of telemedicine). Further, e-prescriptions should include the RMP's name, registration number, date, and mode of consultation.

Professional Duties and Record-Keeping

RMPs must maintain comprehensive records of teleconsultations, prescriptions, and patient data; charge reasonable and transparent fees; and uphold confidentiality while avoiding solicitation or advertisement. Liability exposure may be limited for data incidents and technical failures if it may be construed that reasonable care and adequate safeguards are in place.

Oversight and Enforcement

The Board of Governors and the MoHFW retain oversight powers to revise the drug lists, issue clarifications, and discipline errant practitioners. These enforcement mechanisms ensure that telemedicine remains legally compliant, ethically sound, and aligned with India's evolving digital-health privacy regime.



Conclusion

Telemedicine has emerged as one of the major pillars of the healthcare system after the pandemic crisis. The TPG Guidelines were the first comprehensive regulations that gave a legal basis to digital consultation and ensured patient safety. Nevertheless, the introduction and eventual abeyance of the NMC Code has highlighted the need for a settled regulatory framework.

Besides being a technological innovation, telemedicine is also a challenge from the legal and ethical point of view. A forward-looking regulatory regime - transparent, enforceable, and beneficial to the patient will be able to guarantee that India's healthcare system remains open to everyone, strong, and prepared for the next level of digital transformation.

SECTORAL **PERSPECTIVE**





13

Medical Negligence: The Shifting Legal Terrain

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In recent times, there has been a significant increase in litigation relating to medical negligence claims in India, specifically in the private sector, necessitating that medical practitioners and hospitals develop a holistic understanding of the legal landscape. Factors influencing the rise in medical litigation include increasing access to healthcare, increased access to information through the internet, and rising expectation of outcomes commensurate with the rising costs of healthcare and the commercialisation of the relationship between doctors and patients. Interestingly, while medical

litigation has been more common in emergency medical branches, it is now also increasing in OPD departments like ophthalmology, dental surgery and dermatology.

Against this backdrop, India faces the imminent need to balance the need to secure justice and compensation for patients who genuinely suffer from negligent care, while also preserving the morale and decision-making freedom of medical professionals who operate in complex, high-stakes environments.

India's medical professional-regulation framework was historically anchored in the MCI, a statutory body created under the Indian Medical Council Act 1956; which has now been replaced by the NMC under the National Medical Commission Act 2019. Section 30 of the NMC Act 2019, read with Regulation 8.2 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002 (Ethics Regulations) empowers State Medical Councils to take disciplinary action in respect of any professional misconduct by a registered medical practitioner and a finding of misconduct may lead to a wide range of attendant consequences, including removal from the medical register altogether. The decisions of the State Medical Council can be appealed before the Ethics and Medical Registration Board of the NMC by the concerned doctor, and even by patients.

While there is a disciplinary mechanism in the form of the NMC, the NMC does not grant compensation to patients. As such, compensation can be obtained through the civil remedy available against the tort of negligence, and under consumer protection law. Additionally, punitive action may be sought under the far more rarely resorted to avenue of criminal negligence.

Tort Law Remedy against Negligence

While the concept of medical negligence defies precise definition, the principles of 'negligence', and in particular, professional negligence' was considered in detail by a three-judge bench of the Supreme Court in Jacob Mathew v. State of Punjab; where the Supreme Court held that a professional may be held liable for negligence on one of the two findings, i.e., either that he was not possessed of the requisite skill which he professed to have possessed, or that he did not exercise with reasonable competence in the given case, the skill which he did possess.

In this case, the Supreme Court noted that the test laid down in Bolam v. Friern Hospital Management Committee, has been adopted in India as a touchstone to assess cases of alleged medical negligence in India. The Bolam Test, as is popularly known, is the principle that a doctor does not breach the legal standard of care, and is therefore not negligent, if the practice is supported by a responsible body of medical opinion in the relevant speciality at the material time. The application of the test is therefore often highly reliant on the expert testimony of fellow doctors.

In the UK, the standard for assessing medical negligence has evolved beyond the Bolam Test. In Montgomery v. Lanarkshire Health Board, the UK Supreme Court found that doctors are also under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in the recommended treatment, as well as of any reasonable alternative or variant treatments. Materiality of risk would be adjudged by whether a reasonable person in the patient's position would be likely to attach significance to the risk or whether the doctor was or should reasonably have been aware that the particular patient would attach significance to the risk.

This evolved standard has now been applied by the Supreme Court, though not expressly adopted. In CPL Ashish Kumar Chauhan v. Commanding Officer & Ors., the Supreme Court noted that the duty of care involves not only the professional's assessment of the suitability of the treatment but also the duty to inform the patient of the likely results or risk because the service recipient has to bear the consequent consequences.

It is clear in Indian law that the complainant must make out a case for medical negligence and a doctor cannot be held liable by applying the doctrine of res ipsa loquitor (the thing speaks for itself) merely because the patient has not favorably responded to a treatment or a surgery has failed. Strong circumstantial or documentary evidence is required to attract the principle and reverse the burden of proof.

It is also important to keep in mind that hospitals are vicariously liable for negligence committed by their doctors, nurses and staff in the course of treatment, and the Supreme Court has clarified, in Savita Garg v. National Heart Institute that a hospital cannot be absolved of its responsibility because the doctor in charge or some other staff was negligent.

Remedy under Consumer Protection Law: Deficiency of Service

Medical services fall within the ambit of the Consumer Protection Act 1986 (CPA) and medical practitioners can be regarded as rendering a 'service' under Section 2(1)(o) of the CPA, as held in Indian Medical Association v. V.P. Shantha and Ors.. In this judgment, the Supreme Court observed that medical practitioners do not enjoy immunity from professional liability and can be sued in contract or tort on failure to exercise reasonable skill and care. The very fact that medical professionals are governed by the Indian Medical Council Act would not affect the right of any person who has suffered due to the negligence of a medical professional to seek redress or justify exclusion of medical practitioners from the purview of the CPA.

The above continues to hold good, as the definition of 'service' under Section 2(42) of the Consumer Protection Act 2019 (CPA 2019) includes medical services. Patients can choose to file complaints at the patient's place of residence as well as where the service provider is located, leading to a further simplified process for aggrieved patients. At the same time, hospitals and doctors face an increased burden in terms of being potentially required to defend proceedings across locations.

So does free medical treatment and insurance covered medical treatment constitute a service?

In Indian Medical Association v. V.P. Shantha and Ors, the Supreme Court drew a distinction between medical practitioners and hospitals and nursing homes; where services are: free of charge to all; chargeable to all, and chargeable to all but where certain categories of persons who cannot afford to pay are rendered services free

of charge. While hospitals where services are free of charge to all would not be considered as rendering a service; hospitals where services are free only to certain categories of persons would be considered as rendering a 'service' in respect of both categories of persons.

Similarly, all individual doctors working in hospitals, except in hospitals where treatment is provided to all free of cost, would be providing a 'service' within the meaning of the CPA. It was also clarified that medical treatment covered by an insurance policy or by the patient's employer would also nevertheless constitute 'service' under the CPA.

Applying and clarifying this principle, the Supreme Court has also later held that medical treatment given in a railway's hospital to railway employees at nominal prices as part of their conditions of service would also constitute a 'service' under the CPA; not being free of charge. However, it has been clarified that where a hospital provides treatment free of charge, the medical officer who receives a salary from the hospital would not be considered to be providing a 'service' within the meaning of the CPA, merely because he receives a salary.

Assessment of Compensation

The principles for assessment of compensation or damages for personal injuries laid down by the Supreme Court in Raj Kumar v. Ajay Kumar have been applied to medical negligence to hold that a person is not only to be compensated for the physical injury but also for the loss suffered as a result of such injury, including his inability to lead a full life, enjoy normal amenities he would have enjoyed, and his inability to earn as much as he used to earn. In Malay Kumar Ganguly v. Sukumar Mukherjee, the Supreme Court emphasised that the cumulative effect of medical negligence must be seen, and the court should consider loss of earning or profit already suffered or likely to be suffered in future.

While the pecuniary head for compensation includes loss of earning potential, medical expenses including future medical expenses, and transportation expenses; non-pecuniary heads include compensation computed for mental and physical pain and suffering, including in the future, loss of amenities of life such as loss of marital bliss, loss of expectancy, inconvenience, hardship, discomfort, disappointment and mental agony.

The Supreme Court has recently elaborated upon the concept of just compensation in Jyoti Devi v. Suket Hospital & Ors. and emphasised that it must be considered in the facts of each case, as the idea of compensation is based on restitutio in integrum, i.e., to restore receiver of compensation back to a position where he would have been had the loss not occurred. Compensation must be adequate, fair and equitable.

Criminal Negligence

The majority of cases dealing with imposition of criminal liability on medical service providers are under the Indian Penal Code 1860 (IPC). Here, Section 304A deals with death due to negligence, and Sections 337 and 338 addresses acts that cause hurt or grievous hurt by rash or negligent acts. These sections have now been replaced by Section 106, 125 and 126 of the BNS, respectively. In Jacob Mathew, the Supreme Court clarified the distinction between negligence as a tort and a crime, observing that in tort, the extent of

liability is determined by the amount of damages incurred, whereas in criminal law, it is the amount and degree of negligence that is determinative; and negligence must be gross and of a high decree to invite criminal consequences. It also laid down important guidelines regarding criminal prosecution in medico legal cases, requiring mandatory review by a medical board prior to registration of an FIR in such a case and mandatory preliminary enquiry prior to the launch of investigation. Unfortunately despite this, we have seen that this process is not strictly followed by police in all such cases.

As opposed to the erstwhile Section 304A of the IPC, Section 106 of the BNS enhances punishment from imprisonment or fine, to imprisonment for a term which may extend to five years and fine; and clarifies that if such act is done by a registered medical practitioner while performing a medical procedure, he shall be punished with imprisonment which may extend to two years and also be liable to fine.

While Section 106 of the BNS clearly specifies a gradation of liability and prescribes a lower term of imprisonment for a medical practitioner found guilty; it also makes imprisonment mandatory upon a finding of guilt under this section. While the practical impact of the Section remains to be observed, the harsher provision has raised widespread concern within the medical community.

Further, with the introduction of a specific section dealing with the requirement of a preliminary enquiry in the form of Section 173(3) of the BNS, which requires preliminary enquiry where information pertains to cognisable offences punishable by imprisonment of three to five years; the status of whether the judicially laid down guidelines requiring mandatory preliminary enquiry in cases of medical negligence continue to apply has become unclear; as the same may now be considered overridden by the wording of the statute.



Conclusion

The legal framework governing medical liability in India is not static, and has steadily expanded in scope, becoming increasingly attentive to both patient rights and professional accountability. With the interplay of tort principles, consumer protection law, evolving judicial standards on disclosure and informed consent, and a revised criminal law regime under the BNS, doctors and hospitals today operate within a progressively more demanding legal environment, and the expectations placed on medical professionals now extend beyond clinical proficiency to encompass documentation, communication, and risk disclosure.

Institutional oversight is key, requiring robust internal protocols, standardised informed-consent practices and clear record keeping, as well as liability insurance, which have become essential risk-management tools. A comprehensive understanding of the legal landscape is key to informing best practices that can be invaluable in addressing liability concerns.



14

Product Liability for Medical Devices

Anand Mehta
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The concept of product liability refers to the legal responsibility of manufacturers, sellers, and service providers to compensate consumers for harm caused by defective products. This becomes particularly critical because medical devices directly impact the well-being of patients. A defective device can cause injury, disability, or even death, making the regulation and accountability framework around such devices extremely important.

Legal Framework for Medical Devices in India

Under Indian law, medical devices were historically regulated directly under the D&C Act as 'drugs'. There were no specific rules or regulations for the same. Over time, medical devices became more complex, and a need was felt for specific rules to be framed. Accordingly, the government framed the Medical Devices Rules 2017 (MDR), under Section 3(b) of the D&C Act.

A medical device has been defined very broadly, to include:

- In vitro diagnostic devices and surgical dressings, bandages, sutures, staples etc.
- Mechanical contraceptives and disinfectants notified in the Official Gazette
- Any other device notified by the Government from time to time.

This definition ensures that medical devices ranging from simple thermometers to complex implants and pacemakers fall under regulatory oversight.

Under the D&C Act read with the MDR, the Central Drugs Standard Control Organisation (CDSCO) is the regulatory authority that supervises the manufacture, import, clinical investigation, sale, and post-market monitoring of medical devices in India. The MDR classify devices into risk-based categories (Classes A to D, from lowest to highest risk) and require manufacturers to obtain certification prior to marketing any device. The rules also impose post-market obligations, including mandatory reporting of adverse events, maintaining batch samples, and initiating recall processes if a device is found to be unsafe.

These rules reflect the emphasis on safety, quality control, and continuous oversight in the medical device regulatory regime.

Product Liability under MDR

The MDR requires manufacturers and licence holders to ensure ongoing compliance not only at the stage of manufacture and approval, but also after the device has entered the market. The licence holder is required to report any suspected unexpected serious adverse event to the licensing authority within a prescribed period. Further, where any batch of a medical device has been found to be non-conforming with the standards laid down under the D&C Act and the MDR, the licence holder must withdraw the remainder of that batch from sale, and recall products already issued from that batch. Additionally, the licence holder is required to maintain a reference sample from each batch of medical devices for a fixed period after expiry. Moreover, where there is contravention of any provision of the Act or these Rules, the Licensing Authority may suspend or cancel the licence after providing an opportunity to be heard.

Similarly, where the medical device is imported, the authorised agent is required to inform the licensing authority of any regulatory action taken in another jurisdiction, including withdrawal, restriction, or cancellation of authorisation, and must stop further marketing of such device. Where the Central Licensing Authority finds that the device does not conform to the Act or the Rules, it may direct

that the device or its batch be recalled from all points of distribution, including hospitals.

Enforcement and Penalties

In cases where contravention of the regulatory provisions has occurred, the medical devices in question may be subject to confiscation and the Court may order the disposal or destruction of such devices where they are found not to be of standard quality, at the cost of the license holder. Additionally, the manufacturer or authorised agent is required to voluntarily initiate recall procedures where they have reason to believe that the device may pose a risk to patient safety, and must inform the competent authority of the recall and the actions taken to prevent risk.

Product Liability under the Consumer Protection Act 2019

The CPA 2019 is a legislation aimed to protect consumers. The CPA 2019 applies broadly to all goods and services unless specifically exempted, and since no exemption has been issued in relation to medical devices, they fall squarely within the ambit of the Act. Further, patients have been held to be 'consumers' under the CPA 2019, and doctors, hospitals, clinics have been held to be service providers. It expressly recognises 'product liability' and defines it as the responsibility of a product manufacturer, product seller, or product service provider, (depending on the circumstances of the harm) to compensate a consumer for any harm caused. The term 'harm' in relation to product liability includes personal injury, illness, death, damage to property (other than the product itself), and mental agony resulting from such injury, while excluding commercial or economic loss. Further, Section 2(35) of the CPA 2019 defines a product liability action as a complaint filed before the relevant consumer commission to claim compensation for such harm.

Chapter VI of the CPA 2019 titled 'Product Liability' sets out specific grounds on which liability may arise. A product manufacturer is liable if the medical device contains a manufacturing defect, is defective in design, deviates from manufacturing specifications, does not conform to express warranty, or fails to include adequate instructions or warnings regarding correct usage. This strict liability applies even if the manufacturer can prove that they exercised all possible care or were not negligent. This aspect is particularly relevant in the medical device sector, where failure to provide complete, accurate, and comprehensible usage instructions can itself constitute negligence.



This position is illustrated by the landmark matter where a leading multinational company manufactured hip implants that were found to have inherent design defects leading to metal debris release, severe complications, and the need for early revision surgeries in numerous patients. Although the implants had been imported pursuant to a valid licence issued by the Drugs Controller General of India, subsequent data from various jurisdictions highlighted alarmingly high failure rates. The Ministry of Health constituted an expert committee which confirmed the defect and recommended that the manufacturer provide compensation for pain, suffering, disability, and loss of income. The National Consumer Disputes Redressal Commission (NCDRC) also held that patients who underwent premature revision surgeries were entitled to a minimum assured compensation, with scope for higher awards where specific medical harm was established.

Herein, NCDRC relying upon Divisional Controller, KSRTC v. Mahadeva Shetty emphasised that compensation under the CPA 2019 must be full and adequate, going beyond replacement of the product or reimbursement of treatment costs, while also aligning tort-based principles of bodily injury with consumer protection remedies. This further demonstrates that the CPA 2019 operates in tandem with regulatory actions, such as cancellation of import licences, to ensure accountability where a medical device is defective in its design or performance.

The CPA 2019 also distributes responsibility along the supply chain. A product seller who is not the manufacturer may be held liable if they exercised substantial control over manufacturing, testing, packaging or labelling of the device, or



if they altered or modified the device, provided warranties independent of the manufacturer, or failed to pass on warnings or instructions issued by the manufacturer. This becomes significant in cases where importers, distributors, or retailers handle medical devices without ensuring that the requisite CDSCO instructions and safety disclosures accompany the product.

Similarly, a product service provider may be liable if services related to installation, calibration, use, repair, or maintenance of the device are deficient or carried out negligently, which is directly relevant to hospitals and diagnostic centres where device usage, upkeep, and monitoring affect patient safety.

A pertinent example of this scope of liability is the case of Siddharth Yagneshbhai Panchal v. Sanjivani Super Speciality Hospital Pvt. Ltd. & Ors., where the Gujarat State Consumer Disputes Redressal Commission (SCDRC) held the hospital and doctor liable after the metal plate implanted in the patient's hand fractured soon after surgery. The Commission held that the patient, being a layman, had no role in

selecting or purchasing the implant and relied entirely on the hospital to provide a device of proper standard and quality. Since the hospital had procured and supplied the implant, and the patient had no direct dealing with the manufacturer, liability rested with the hospital and doctor for failing to ensure that the device met required safety and performance expectations.

In Paras Hospitals v. Rishi Kumar Jain, the NCDRC observed that there was no evidence that the implanted CRT-D device in question was defective, expired, infected, or inappropriately selected, and therefore held that no medical negligence was established. However, the hospital was still held liable for deficiency in service because the high-value implant was not shown to the complainant before implantation; and observed that it is expected that high value critical medical implants be shown to the affected parties before due process. In this case, despite there being no proven fault in the device itself, the failure to follow expected disclosure practices was sufficient to attract liability.

Once liability is established, Section 39 empowers the Consumer Commission to order a wide range of remedies, including removal of defects, replacement of the device with one free from defects, refund of price along with interest, compensation for injury suffered, punitive damages, discontinuation of hazardous practices, withdrawal of unsafe products from the market, or even cessation of manufacture of hazardous goods. Where harm has been suffered by a large number of consumers who cannot be individually identified, the Commission may order compensation as a collective remedy, with the minimum payable amount being not less than 25% of the value of defective goods sold.

It is also significant to mention that, in addition to individual product liability actions, the CPA 2019 now allows for class actions under Section 35(1)(c), and one or more consumers can file a complaint on behalf of other similarly placed consumers. This marks an important expansion of consumer remedies beyond individual claims under the earlier regime, particularly in situations where the same defect or deficiency affects multiple consumers.

Separately, the Central Consumer Protection Authority (CCPA), as established under the CPA 2019, has been vested with wide powers to protect consumer interests at a systemic level. The CCPA has the power to inquire or cause an inquiry to be made into violations of consumer rights or unfair trade practices, either upon receipt of a complaint, upon directions from the Central Government, or even suo motu, emphasising its regulatory function. The CCPA may issue orders for r call of unsafe or hazardous products, reimbursement to consumers, and discontinuation of unfair practices.

Thus, in the case of medical devices, the CPA 2019 provides a comprehensive statutory mechanism to assign legal responsibility, based not only on the existence of a defect in the device but also on the conduct and obligations of every entity involved in making the device available for patient use. The framework ensures that liability is not limited to the manufacturer alone but also extends to sellers and service providers where their conduct or omissions contribute to the harm suffered. It further enables both individual and collective consumer remedies, including representative actions and regulatory intervention where consumer interests are affected on a wider scale.

Other Remedies

Whilst the above legal framework is available, depending on the nature of the violation and seriousness of the adverse impact it has on a patient, the patient may also exercise the right to file a complaint of criminal negligence. A hospital or doctor may also be sued for tort before the appropriate court of law.

Conclusion

India's medical device framework is primarily shaped by two complementary regimes, the MDR, which regulates manufacturing quality, licensing and post-market oversight; and the CPA 2019, which governs when patients may hold hospitals or doctors liable for harm or deficiency in service. Although the MDR primarily binds man facturers and licensees, recent decisions show that obligations for healthcare providers are steadily expanding beyond merely clinical judgment and expanding to diligence in procuring medical devices and transparent communication about the devices used.

It is also clear that the emergent principle is that hospitals and doctors must also exercise diligence in procurement, documentation and patient communication. While medical devices are governed by the MDR, hospitals may be exposed to liability for deficiency service where products are procured without adequate care or used without proper disclosure to patients.

As more patients and their relatives become aware of their legal rights and remedies, manufacturers, hospitals and doctors are likely to face a significantly higher risk of litigation going forward.





15

Elderly Care

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Yash Dawda

India is currently experiencing a dual demographic shift not only in terms of population growth, but also through accelerated ageing. As of 1 July 2022, there are approximately 149 million individuals aged 60 years and above, constituting about 10.5% of the national population. What is particularly noteworthy is that projections indicate that by 2050, this proportion will nearly double to 20.8%, with the elderly population reaching an estimated 347 million . This significant demographic transition necessitates the formulation of comprehensive legal and policy response that can address the multifaceted needs of the ageing population, including access to affordable and regular healthcare services and the protection and enforcement of their rights.

While India has indeed taken steps in this direction, current measures are not yet proportionate to the scale and complexity of the demographic transition. For instance, programs such as the 'National Programme for Healthcare of the Elderly' aim to strengthen the healthcare infrastructure for senior citizens. However, several challenges remain unresolved—particularly around accessibility, regional disparities, and awareness gaps about existing facilities and entitlements.

Moreover, many elderly-focused policies tend to be qualified by socio-economic criteria, such as limiting benefits to those from below poverty line families or unorganised sector workers. Although such targeting may be justified from a resource allocation standpoint, it can also lead to the exclusion of large segments of the elderly population who may not fall within narrowly defined categories but still face vulnerability. What is required, therefore, is a broader and more inclusive policy outlook one that recognises the rights and needs of all, irrespective of their income or employment history.

These are just some of the challenges confronting our current policies and programs. Addressing them meaningfully will require not only internal reforms but also a willingness to learn from global best practices. For example, developed jurisdictions offer instructive models in areas such as guaranteed access to daily care, protection from age-based discrimination and abuse, age-friendly employment policies, and entitlements to routine healthcare. This article undertakes a comparative analysis of such international legal frameworks, with the aim of identifying adaptable models that can be integrated into the Indian context—tailored to align with the country's demographic realities, economic constraints, and cultural norms around ageing and elder care.

Global Landscape

An overview of relevant statutory and policy frameworks from jurisdictions noted for their progressive eldercare regimes is provided below.

USA: Emphasising Rights and Healthcare Access

Older Americans Act (OAA): Enacted in 1965, the OAA supports services like meal delivery, transportation, and in-home care to help older Americans live independently. The act aims to provide comprehensive service delivery to the elderly, ensuring they receive support in various aspects of their daily lives. The OAA offers a variety of health and social services for individuals aged 60 and older, including personal care, transportation, congregate and home-delivered meals, caregiver support, long-term care ombudsman services, and programs to prevent abuse. It also provides part-time community service opportunities for unemployed low-income individuals aged 55 or older.

United Kingdom (UK): A Rights-Oriented and Holistic Approach

Care Act 2014 (Care Act): This legislation ensures local authorities meet the care needs of older people while emphasising dignity and well-being. The Care Act outlines the responsibilities of local authorities in assessing and providing for the care needs of their elderly residents, promoting their independence and quality of life.

Equality Act 2010 (Equality Act): It prevents age-based discrimination, ensuring older individuals have equal access to healthcare, services, and employment. It covers various aspects of discrimination, including direct and indirect discrimination, harassment, and victimisation.

National Health Service (NHS): The UK offers universal healthcare through the NHS, with local authorities providing other social care services. The UK's population is ethnically diverse, and care systems are changing to identify the value of culturally responsive, person-centred care. This type of care personalises services to meet the individual's distinct cultural, religious, and personal context, promoting inclusion, dignity, and respect. Further there is a vigorous trend toward community and age-friendly settings.

Day centres, social clubs, and intergenerational programs are initiatives that try to counteract loneliness and encourage active engagement in society. The integrated system in the UK further incorporates physical, emotional, and social care, recognising the complete range of seniors' needs.

Sweden: A Comprehensive and Holistic Senior Care System

Social Services Act 2001 (SSA): The SSA mandates municipalities to provide care and assistance to older people, including rehabilitation and support for independent living. It emphasises the right of elderly individuals to receive care thatpromotes their dignity and autonomy. The national goals for elder care mandate municipal authorities to ensure that elderly individuals live active, independent, and respected lives with access to quality care. Under the SSA, social services must provide outreach services and inform the target citizens of their rights and opportunities for care, tailored to their needs. However, the new Social Services Act is set to replace the SSA with effect from July 2025.

In Sweden, elderly care is seen as a social right subject to national law and financed to a great extent through local taxation. Municipalities enjoy broad powers of organisation and provision of care, such as home help, nursing, and community support. Sweden gives top priority to keeping older people in their homes for as long as possible, with comprehensive support for home care. The system is universal, with few out-of-pocket expenses for users. Such a system promotes autonomy, dignity, and social interaction, thereby maintaining an appropriate balance between their medical and social needs.

Australia: A national framework with a focus on consumer choice

Aged Care Act 1997: This legislation lays the foundation for Australia's senior care system, which includes both residential care and home care options. It outlines the responsibilities of the government in providing care services and sets quality standards for care providers. The new Aged Care Act, set to be effective from 1 November 2025, is designed to overhaul and unify the legislative framework governing aged care in Australia, replacing several existing laws including the Aged Care Act 1997, the Aged Care (Transitional Provisions) Act 1997, and the Aged Care Quality and Safety Commission Act 2018.

Australia's aged care is informed by its multicultural environment. Service providers are incentivised to provide culturally responsive and safe care, particularly to Indigenous and immigrant older people. This includes respect for languages, customs, and religious practices.

Key takeaways for India

In India, care of the elderly has traditionally been family centered. Elders live with their children and extended family members, where they receive care, respect, and companionship. Nonetheless, rapid urbanisation, migration, and evolution in family patterns are undermining this tradition. Increasingly, elders are found living either entirely alone or with minimal familial presence. In response, India has initiated programs like the National Programme for Health Care of the Elderly, designed to deliver affordable and accessible long-term care, preventive care, and support to family caregivers. Increased focus is being placed on incorporating mental health, social well-being, and psychological support into care systems.

The Government of India has launched a variety of schemes to help the elderly, with the aim of guaranteeing financial security, affordable healthcare, and general well-being among senior citizens. Below is an overview of some of the most important government schemes for seniors, including their goals and advantages:

Senior Citizens Savings Scheme: This is one of the most sought-after investment schemes among people above 60 years of age. It provides a safe route towards a steady income post-retirement, with a high interest rate of 8.2% per annum, a five-year tenure (renewable by three years), and a maximum deposit amount of INR 30 lacs. The plan offers quarterly interest payments and Section 80C tax advantages under the Income Tax Act 1961, giving retirees a secure option for financial protection and predictability.

Indira Gandhi National Old Age Pension Scheme and Rashtriya Vayoshree Yojana: Designed to create a social safety net families below the poverty line, the Pension Scheme provides a monthly pension to those who are 60 years and above. Beneficiaries get INR 200 per month till 79 years and INR 500 per month after that. States tend to provide additional top-ups over central assistance. Alongside this initiative, the Yojana offers free of cost assistive aids like walking sticks, hearing aids, and wheelchairs to citizens above the age of 60. The devices are distributed via assessment camps organised across the country, greatly enhancing mobility and the quality of life among beneficiaries.

Rashtriya Swasthya Bima Yojana: Introduced by the Ministry of Labour and Employment in 2008, this was designed to provide health insurance to families below the poverty line, specifically those working in the unorganised sector. It offers cashless hospitalisation benefits for secondary care up to INR 30,000 per family (unit of five) per year, covering a wide range of medical conditions and procedures. Notably, pre-existing diseases are covered from day one, and beneficiaries receive transportation allowances for hospital visits. The scheme is entirely government-funded, with the enrolment process kept simple through biometric smart cards issued at enrolment camps at a nominal fee of INR 30. While this initiative has now been largely subsumed under the AB PM-JAY, its legacy remains relevant, especially in regions where the rollout is still evolving.[KCO8.1]

Golden card for senior citizens: Under the AB PM-JAY scheme, citizens aged 70 and above benefit from health insurance coverage of up to INR 500,000 per family per annum. This program aims to provide financial protection and peace of mind by covering hospitalisation and treatment for serious diseases at empanelled hospitals. Applications for this coverage can be submitted through common service centres or directly via the AB PM-JAY portal.

Other schemes at the state level: At the state level, various ancillary schemes complement national efforts. For example, Maharashtra has introduced the Chief Minister Vayoshree Scheme, which offers one-time financial assistance to senior citizens aged 65 years and above. This support helps them purchase medical equipment or pursue training at mental health and yoga institutes.

Taken together, these schemes address the financial and healthcare needs of India's elderly population, reflecting a clear commitment to ensuring security, dignity, and an improved quality of life during their golden years.

Challenges Ahead

India faces several challenges in senior care, especially due to its vast population and reliance on family structures for caregiving coupled with issues around the enforcement of these schemes. However, the nation can learn from global best practices and implement reforms that would benefit its senior citizens. Some of these include:

Developing a state specific and integrated framework: While the Maintenance and Welfare of Parents and Senior Citizens Act 2007 (MWPSC Act) provides a foundational legal structure addressing basic maintenance and residential needs, a one-size-fits-all national policy may not fully capture the diverse requirements of elderly care across India's various states. Therefore, adopting state-specific legislation that complements a broad national framework could prove more effective.

Such an approach would allow each state to clearly define the roles and responsibilities of government agencies, healthcare providers, and community organisations in ways that align with local customs and social structures. Consequently, this would facilitate the delivery of services ranging from healthcare and social support to legal protections, in a manner that is both culturally sensitive and rights based.

Embracing consumer-centered care: Australia's emphasis on consumer-directed care provides seniors with greater autonomy in selecting the types of services they need. India could benefit from introducing similar flexibility, enabling elderly individuals to exercise more control over their care preferences. Furthermore, adopting culturally grounded and community-led models similar to those in Australia could help foster a stronger sense of belonging and support among older adults.

Integrating health and social services: As exemplified by Sweden and the UK, integrating health and social services ensures seniors receive coordinated care addressing not only their medical but also their emotional, psychological, and social needs. Achieving this would require dismantling existing silos between health and social welfare departments and fostering deeper collaboration among healthcare providers, social workers, and community organisations. Such a unified system could improve outcomes by delivering more consistent and holistic support to older individuals.

Limits on universalism: Financial means are a strong predictor of successful ageing. In means-tested or privatised systems (such as the US and parts of the UK and Australia), money allows individuals to enter for more upscale care, higher-quality facilities, and more options. Even in a country with a universal system like Sweden, those with resources can complement public care with private care. Healthcare systems tend to mirror—and at times exacerbate—wider social disparities. Although ageing itself is non-discriminatory, the availability of care, quality of life, and potential for social engagement depend on economic and social position. This fact makes it critical to have policies that deal not only with medical requirements but also with economic security, social integration, and equity.

Strengthening legal protections: Although the MWPSC Act establishes a basic legal framework for maintenance and support,

India could benefit from more robust and explicit legislation aimed at preventing age-based discrimination, exploitation, and elder abuse—akin to protections under the Equality Act in other jurisdictions. This would entail dedicated laws coupled with stronger enforcement mechanisms designed to safeguard the rights and dignity of older adults across all facets of life, including employment, access to services, and protection from financial and physical abuse.

Conclusion

Elderly care is at a turning point across the globe. India's cultural heritage of family care is strained by social change, while in the west there is tension between public provision and individual responsibility. The trend toward holistic care—covering physical, mental, emotional, social, and spiritual needs—is making progress everywhere. India must aim to construct systems that respect the dignity and potential of all elders, societies need to invest not only in medical care but also in social infrastructure, cultural competence, and policies that alleviate inequality, in addition to its very successful family centric approach.

Subsequently, focus on developing a consolidated legal framework that clearly defines the rights of the elderly and the corresponding obligations of the state governments and their agencies, caregivers, and healthcare institutions. Legislative reforms should include legal recognition of consumer-directed care models, and mechanisms for regulation and oversight of elderly care services. Such measures will not only address systemic gaps but will also give legal force to the constitutional promise of dignity, equality, and social justice for all citizens, including the elderly.

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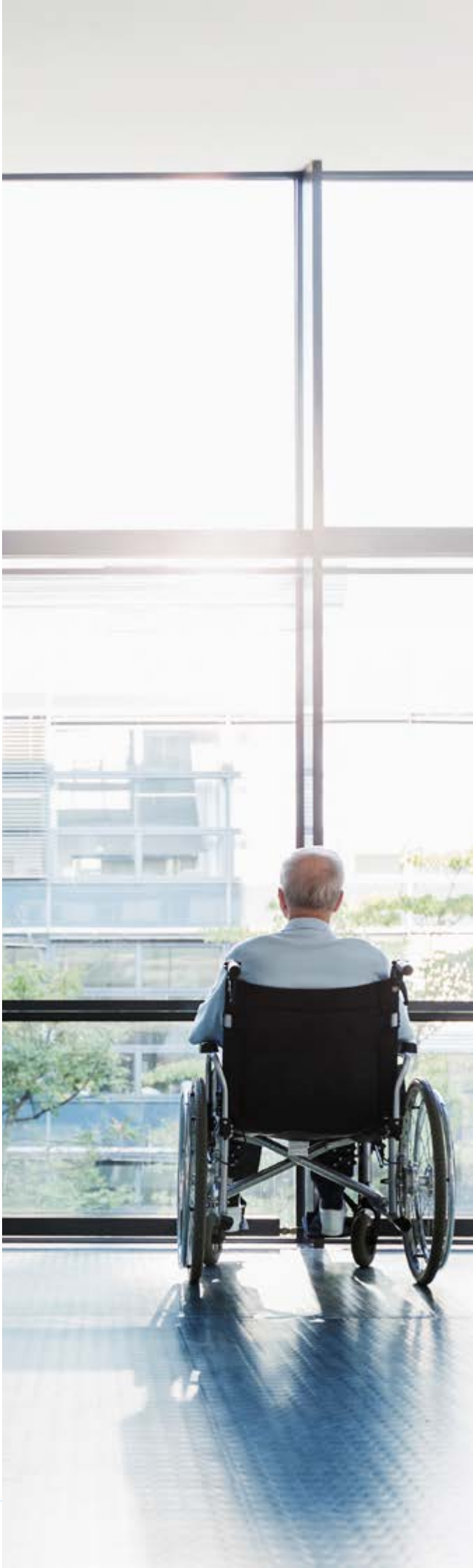



16

Medical Tourism: A Jurisprudential Perspective

Anand Mehta
Hansaja Pandya

In financial year 2023, the tourism sector's contribution to India's GDP jumped back to the pre-pandemic level of 5% and created 7.6 crore jobs. India earned USD 28 billionin foreign exchange earnings through tourism. More specifically, medical travel sector has witnessed significant growth, with India issuing 23,30,345 medical visas and market valuation projected to reach USD 13.42 billion by 2026. However, India's tryst with medical tourism goes back to roughly 5000 years where historians find evidence of yoga retreats and meditation centres.

Recognising the immense potential in the medical tourism sector, the Union Budget 2025-26 aims to prioritise medical tourism by leveraging India's traditional wellness systems like Ayurveda and Yoga on one hand and the world class medical expertise, cost-effective treatments and technological advancement on the other. Based on these strengths, the government has promulgated the 'Heal in India' initiative as part of the Union Budget 2025-26, in partnership with the private sector, to enhance India's position as a premier global healthcare destination.

Despite emphasis, boosting medical tourism would require the Indian legislatures to navigate through various legal challenges like absence of uniform regulations on medical negligence and/or malpractice across jurisdictions and navigating data privacy concerns of medical tourists. In this article we have set out a detailed analysis of these two major legal challenges faced by the medical tourism industry in India: legal recourse for medical negligence and/or malpractice; and data privacy concerns in cross-border information sharing, along with a comparative analysis of the legal framework implemented in other competitive jurisdictions to mitigate these legal challenges.

Legal Recourse for Medical Negligence and Malpractice

Pursuing legal action for medical malpractice and/or negligence can be challenging due to differences in legal systems, language barriers, and the complexity of cross-border litigation. This can leave patients without adequate remedies in cases of substandard care. Absence of a standardised practices and uniform laws across nations impede a patients' ability to exercise their right to sue in cases of medical malpractices and/or negligence arising from medical tourism.

A snapshot of how competing jurisdictions have evolved their legal jurisprudence to address these issues are provided below.

Jurisprudence in the USA: Countries like the USA are stepping up to protect foreign patients by issuing formalised 'Medical Tourism Guideline' prepared by the American Medical Association to inform the patients of their rights and legal recourse prior to agreeing to travel outside the country.

Jurisprudence in Canada: The general public sentiment in Canada has been to oppose any form of medical compensation to foreign tourist. The approach increasingly wants foreign patients to bear the full costs of their decisions, even in cases where the medical process takes an adverse turn.. Such concerns arise in a pooled and universal healthcare system like Canada's where government's healthcare budget is fixed, and the limited health resources are to be shared by all. Canadian citizens feel that they shouldn't be burdened by the costs that the foreign patients impose without contributing to the pool.

Jurisprudence in India: The ethico-legal concerns which pre-dominantly arise out of a pooled and government run healthcare system are not prevalent in India. Further, existing legislations and legal jurisprudence, both are in tandem offering remedies to foreign patients on an equal footing as the Indian citizens.

Outline of the legal remedies available to a foreign patient in India:

Indian Legislations

- The CPA 2019 entitles any foreign patient, who hires services of a doctor for a consideration is to file a suit for compensation against the medical institution and/or the doctor.
- The Civil Procedure Code 1908 entitles an aggrieved party (irrespective of the party's citizenship status) to commence execution proceedings in cases where the defendant has not rendered the compensation to the aggrieved party as per the orders of the court. In such execution proceedings, the court has wide authority including the power to seize and sell any property belonging to the defendant to ensure that the aggrieved party is paid due compensation.
- India's foreign exchange laws permit authorised dealer banks to rely on court orders and defendant to remit the compensation amount to the aggrieved person abroad, even if such amounts exceed the remittance limits set by the RBI.
- BNS contains specific provisions for medical negligence under section 106 which provides that, if the act is committed by a registered medical practitioner (i.e., an individual holding recognised qualifications under the National Medical Commission Act 2019 and registered in the National Medical Register or a State Medical Register) while performing a medical procedure, such medical practitioner is punishable with imprisonment of up to two years, along with a fine. Previously, under the IPC, there was no such specialised provision to deal with cases of medical negligence and these were treated under the generalised section 304A of the IPC dealing with death caused by any rash or negligent act. Such strict criminal liability for cases of medical negligence provides better legal recourse to the patients and increase the accountability of the doctor and medical institutions.

Indian Judicial Precedents

The Indian judicial system has supplemented the legislations by establishing the court's jurisdiction and authority to adjudicate cases of medical negligence and/or malpractice that have occurred within the territory of India irrespective of the nationality of the patient. The Indian judiciary has pre-dominantly relied on the principles of law of torts to assign liability in cases of medical negligence and malpractice.



- Principle of Vicarious Liability: The torts law principle of 'vicarious liability' has been applied by the Indian courts, time and again to hold the medical institutions accountable for any injury or loss or life arising due to any medical malpractice,negligence ordeficiency of services on the part of the consultant doctors/nurses employed at such hospital. The courts have on multiple instances struck down any argument that allow hospitals to escape liability by defining themselves as mere 'infrastructure providers'. The hospitals are responsible on behalf of the staff they hire and hence are vicariously liable for any breach by its staff in exercising the expected standard of care; and defective equipment operated by the hospital.

The court attributes vicarious liability based on the well-settled principal of law of torts that, the doctor or hospital was negligent in exercising their 'duty of care' towards the patients. The duty of care is deemed to be breached once the patient is able to prove that 'but for the said breach, no injury would have been suffered'.

- Determination of Compensation: The Indian courts have, adopted a standardise approach by relying on three key factors to determine the quantum of compensation that the doctors and/or the hospital are liable to pay to the patient or its heirs: pain and suffering endured by the patient (including duration and intensity) as a result of the negligence or malpractice; loss of earning or future earning; and expenses incurred for the medical treatment. The courts have, in certain cases also divided and apportioned the compensation amount between a doctor the hospital he is engaged at, based on the degree of negligence attributable to each doctor and the hospital.

The Indian judiciary has shown consistency in placing reliance on torts law principles of negligence and vicarious liability and by doing so, Indian judiciary has reinforced the responsibility of hospitals not only for the actions of their staff but also for the safety and functionality of the equipment they provide. This comprehensive approach underlines India's commitment to ensure that the foreign patients are treated fairly and their legal rights are upheld, protected and enforced, when they experience medical negligence, substandard services, or malpractice by doctors or hospitals.

Data Privacy Concerns in Cross-Border Information Sharing

Medical records are essential for facilitating communication between healthcare professionals and ensuring continuity of treatment, including post-operative care after a foreign patient returning to their home country. However, sharing medical records across borders can be challenging since the standards of data protection differ over jurisdictions. Few instances of difference in data protection standards amongst other countries are set out below:

Jurisprudence in European Union (EU): The General Data Protection Regulation (GDPR) prohibits the transfer of data from the EU to a recipient outside of the EU unless the recipient country provides protection that is comparable to the EU. The European Commission has so far recognised Andorra, Argentina, Canada (commercial organisations), Faroe Islands, Guernsey, Israel, Isle of Man, Japan, Jersey, New Zealand, Republic of Korea, Switzerland, the United Kingdom's regime under the GDPR and the implementing decision (EU) 2021/1773 of 28 June 2021, the United States (commercial

organisations participating in the EU-USA data privacy framework) and Uruguay as providing adequate protection.

Jurisprudence in USA: The USA also has a privacy protection in the Health Insurance Portability and Accountability Act of 1996 which protects all health information that is part of an individual medical record and requires entities holding such information to keep track of disclosures they make third parties in print or electronic form. Privacy stipulations require standards to be set to secure and protect electronic information.

Jurisprudence in Canada: Canada has two federal privacy laws, the Privacy Act and the Personal Information Protection and Electronic Documents Act (PIPEDA). PIPEDA applies to the private sector and similarly regulates the collection, use or disclosure of personal information in connection with commercial activities.

In order to navigate this issue, the data transfer process is typically managed by medical tourism facilities in the destination country or by a facilitator agent. The facilitator acts as an intermediary between the patient and the healthcare provider in the destination country and given the difference in data protection standards, the facilitator agent (who is in direct contact with the patient and has access to medical records of foreign patients), must prioritise the confidentiality and security of the patient's information.

Execution of medical tourism agreements may be considered between the hospital and the facilitator whereby the agreement sets out critical terms of data confidentiality, cross-border sharing, patient referral and payment procedure, exclusion of liability of the hospital and the facilitator in certain cases, and dispute resolution mechanism for the parties involved.

Additionally, Indian healthcare professionals should undertake certain steps at an organisation level to align their private practices with extraterritorial standards. These steps include execution of robust data confidentiality agreements to safeguard patient privacy and reduce the risk of legal action arising from data breaches.



Conclusion

India's burgeoning medical tourism sector presents significant opportunities for both economic growth and global healthcare leadership. With its rich history in wellness traditions and world-class medical expertise, India is well-positioned to become a premier destination for medical travellers.

While India's legal jurisprudence on medical negligence and malpractice has substantially evolved, however, it may borrow from the data privacy frameworks of other competitive jurisdictions to implement effective policies that safeguard both patients and healthcare providers.

As the sector continues to expand, it will be essential for lawmakers, the medical community, and the private sector to work together to create a robust and secure environment for medical tourism to thrive.

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CSR and Healthcare

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India has a distinct and pioneering statutory framework for CSR. In most jurisdictions, CSR remains voluntary, however, India mandates it under Section 135 of the Companies Act 2013 where eligible companies and those meeting prescribed thresholds of net worth, turnover, or profitability should spend at least 2% of their average net profits of the preceding three financial years on CSR activities. Schedule VII of the Act provides permissible areas of CSR spending which explicitly includes 'promoting health care, including preventive health care' along with sanitation, nutrition and safe drinking water.

This statutory regime is an attempt to integrate corporate participation into national development goals. The regime also establishes governance obligations such as constituting CSR committees, ensuring disclosures, reporting unspent CSR funds, and conducting impact assessments for major projects. Over time, amendments and accompanying rules have shifted the focus from ad hoc charitable contributions to more systematic, results-oriented social initiatives.

Amongst all permissible areas for CSR spending, healthcare has emerged as one of the most prominent and consistently prioritised CSR sectors.

Healthcare as a Dominant Area of CSR Expenditure

Healthcare has consistently remained one of the largest areas of CSR spending in India, along with education, largely because of the ongoing public health issues and gaps in access to medical services. Trends in CSR data also indicate that a significant and steadily increasing portion of corporate funds continues to be directed towards healthcare initiatives.

Between FY 2014-15 and FY 2023-24, CSR expenditure on healthcare increased significantly. Spending rose from approximately INR 1847.74 crores in FY 2014-15 to over INR 7150.81 crores in FY 2023-24, reflecting nearly a fourfold increase over a decade. Notably, healthcare CSR spending peaked during the COVID-19 years, with expenditure reaching INR 7325.83 crores in FY 2020-21 and INR 8049.49 crores in FY 2021-22, underscoring the sector's importance during public health emergencies.

Recent media reports also confirm that healthcare continues to dominate CSR spending even in the post-pandemic period, along with education. This sustained prioritisation reflects the scale of healthcare needs as well as the perception that health-related CSR has one of the most direct and visible social impact.

Types of CSR Activities in the Healthcare Sector

CSR initiatives in healthcare cover a wide range of activities, strengthening different layers of the healthcare system. A major focus area is preventive healthcare which includes health awareness campaigns, nutrition programs, immunisation drives, and screening initiatives for communicable and non-communicable diseases. These programs do not just address root causes of illness but also help in reducing long-term healthcare burdens.

Another significant category is improving access to healthcare services, particularly in rural and underserved regions of the country.



Companies fund mobile medical units, health camps, telemedicine facilities, and primary healthcare centres to bridge geographical and infrastructural gaps. These initiatives often operate through partnerships with NGOs, charitable trusts, or state health departments.

The most substantial part of the investment is into healthcare infrastructure development. This includes funding for hospitals, diagnostic centres, maternity wards, ICUs, and procurement of medical equipment such as ventilators, dialysis machines, ambulances, and laboratory tools. CSR also supports maternal and child health programs, mental health services, disability care, and sanitation-linked health initiatives.

Impact of COVID-19 on Healthcare CSR

The COVID-19 pandemic profoundly reshaped CSR in India. The pandemic exposed the shortcomings and gaps in India's healthcare system and hence, placed healthcare at the centre of corporate social engagement. The government explicitly recognised COVID-related expenditure as eligible CSR spending, enabling companies to respond rapidly to the crisis.

CSR funds during this period were directed towards oxygen generation plants, ventilators, hospital beds, PPE kits, testing infrastructure, vaccination drives, and public health awareness campaigns. The sharp rise in healthcare CSR spending during FY 2020-21 and FY 2021-22 reflects the scale of corporate mobilisation in response to the pandemic. The pandemic demonstrated that CSR could function as a critical supplementary mechanism during public health emergencies, complementing government



capacity. It also highlighted the importance of flexibility, coordination, and rapid deployment of CSR resources in times of systemic stress.

Geographic Spread of Healthcare CSR Spending

Healthcare CSR expenditure is geographically widespread; however, it reflects patterns of uneven corporate presence and concentration in certain states. State-level data for FY 2023–24 shows significant variation in healthcare-related CSR spending across India.

Maharashtra accounts for the highest healthcare CSR expenditure at approximately INR 2,098.69 crore, followed by Gujarat (INR 570.25 crores), Tamil Nadu (INR 566.57 crores), Uttar Pradesh (INR 480.83 crores), Delhi (INR 462.46 crores), Karnataka (INR 427.57 crores), and Odisha (INR 416.27 crores). Smaller states and Union Territories receive comparatively lower amounts, highlighting regional disparities in CSR fund allocation. The concentration in industrialised states was expected, however, these figures also raise policy questions about the need for better alignment of CSR funds with healthcare needs in underdeveloped and high-burden regions.

Healthcare Companies, CSR, and the Risk of Marketing Benefit

The concern usually comes up when healthcare and pharmaceutical companies undertake CSR activities in the healthcare sector about the potential for indirect marketing or commercial benefit. Indian CSR law and regulatory guidance make it clear that CSR activities should not be used for brand promotion. This tampers with the ethical foundation of CSR.

As a result, it is essential that healthcare companies ensure that CSR initiatives such as treatment programs or hospital support, do not promote specific products for commercial gains. Any perceived conflation of CSR with marketing which is undermining the ethical foundation of CSR and may attract regulatory scrutiny and action.

Best practices to mitigate this risk include implementing CSR through independent trusts or NGOs, avoiding product branding, ensuring transparency in implementation, and focusing on broad public health outcomes rather than company-specific benefits.

CSR as an Enabler of Healthcare Initiatives

CSR has gradually evolved into a key driver of healthcare initiatives by encouraging collaboration between the public and the private sector. This has led to more innovation and focused interventions in healthcare. Companies have helped scale healthcare models, improve public infrastructure, and tackle underlying factors affecting health, such as nutrition, sanitation, and access to clean water through CSR funding.

When aligned with national health priorities and carried out thoughtfully, CSR can widen access to healthcare, lead to better health outcomes, and make the system more resilient. It is not meant to take over the government's role, but rather to support and strengthen the existing public healthcare framework.



Conclusion

India's statutory CSR framework effectively brought companies to participate in the country's healthcare development. Over the years, healthcare has become a key area for CSR spending, evident from steady growth in allocations, the sharp focus during the pandemic, and its presence across states. CSR has played a tangible role in bridging gaps in the healthcare system, including preventive healthcare, building infrastructure, responding to emergencies and supporting innovation.

At the same time, especially in the case of healthcare companies, it is important that CSR activities are carried out with clear ethical boundaries and are not driven by commercial considerations like branding or marketing. When approached with transparency and accountability, CSR can significantly strengthen healthcare efforts and contribute to making healthcare more accessible and equitable in India.

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