INTERNATIONAL JOURNAL OF HUMAN RIGHTS LAW REVIEW
An International Open Access Double Blind Peer Reviewed, Referred Journal

Volume 4 | Issue 6 | 2025 Art. 11

Regulation of Use of AI in the Healthcare Industry in India - An Analysis

Shudharshini E
Law Student,
Tamil Nadu Dr. Ambedkar Law University

Recommended Citation
Shudharshini E, *Regulation of Use of AI in the Healthcare Industry in India - An Analysis*, 4 IJHRLR 160-167 (2025).
Available at www.humanrightlawreview.in/archives/.

Regulation of Use of AI in the Healthcare Industry in India - An Analysis

Shudharshini E
Law Student,
Tamil Nadu Dr. Ambedkar Law University

Manuscript Received	Manuscript Accepted	Manuscript Published
17 Nov. 2025	19 Nov. 2025	25 Nov. 2025

INTRODUCTION TO AI IN HEALTHCARE

Artificial Intelligence (AI) has emerged as a transformative force in the healthcare industry, globally and in India. With its capacity to process vast volumes of data, learn from patterns, and assist in diagnostic, predictive, and administrative tasks, AI is revolutionizing clinical decision-making, patient care, drug discovery, and hospital management. In India, AI is increasingly being used to bridge gaps in healthcare delivery, particularly in rural and underserved areas. Startups and hospitals are deploying AI tools for radiology, pathology, dermatology, ophthalmology, and more. Applications include AI-powered diagnostic tools like Qure.ai for radiology, AI chatbots for mental health like Wysa, and early cancer detection systems like Niramai.

However, the integration of AI in healthcare also raises significant ethical, legal, and regulatory concerns. These include data privacy, algorithmic bias, accountability for medical decisions, and the lack of human oversight. As AI begins to influence life-and-death decisions, regulatory oversight becomes imperative. India currently lacks a comprehensive and specific legal framework regulating the use of AI in healthcare. While some general regulations apply, such as the IT Act, 2000, and data privacy guidelines, there is no clear law that governs medical AI tools' safety, efficacy, or ethical use. This paper aims to analyze the current regulatory landscape, identify gaps, and propose suggestions for the responsible use of AI in Indian healthcare.

CURRENT USE OF AI IN INDIAN HEALTHCARE AND ITS POTENTIAL

The adoption of Artificial Intelligence (AI) in India's healthcare sector is primarily being driven by three key factors: the pressing need for affordable medical care, a significant shortage of trained healthcare professionals, and the rapid digitalization of health data across the country. AI-powered tools are increasingly being utilized to address these challenges across various domains. In

diagnostics, AI models are assisting doctors by swiftly and accurately analysing medical images such as X-rays, MRIs, and CT scans; a notable example is Aravind Eye Hospital's use of AI for diabetic retinopathy screening. In the realm of telemedicine, AI-enabled chatbots and triage systems are effectively managing patient loads by conducting preliminary assessments before patients consult with doctors. AI is also proving instrumental in drug discovery and genomics, helping accelerate clinical trials, predict molecular behaviours, and customize treatments based on individual genetic profiles.

Moreover, wearable devices and mobile applications integrated with AI capabilities are being employed to monitor health metrics and predict disease risks, thus enabling preventive care. On the administrative front, AI is enhancing hospital efficiency by streamlining operations such as patient record management, billing, and resource allocation. However, despite its transformative potential, the deployment of AI in Indian healthcare largely operates within a regulatory vacuum. There are currently no standardized protocols for validation, clinical testing, or ethical clearance of these AI tools. Most operate without formal oversight from key regulatory bodies such as the Indian Council of Medical Research (ICMR) or the Central Drugs Standard Control Organization (CDSCO), raising significant concerns about patient safety and system accountability.[1]

EXISTING REGULATORY FRAMEWORK AND GAPS

The regulation of Artificial Intelligence in healthcare in India is currently governed by a fragmented and indirect legal framework. While several laws and policy instruments touch upon relevant aspects, none specifically or comprehensively address the unique challenges posed by AI in medical contexts. The key existing frameworks are as follows:

1. Information Technology Act, 2000

The IT Act serves as India's primary legislation governing digital infrastructure, cybercrime, and electronic data. Although it includes provisions on data protection and electronic records, it does not specifically regulate AI technologies, especially those involved in critical sectors like healthcare. Notably, it lacks provisions concerning algorithmic accountability, transparency, or liability for automated decisions made by AI systems (Ministry of Law and Justice, 2000).

[1] Central Drugs Standard Control Organization (CDSCO). (2017). *Medical Devices Rules, 2017*. https://cdsco.gov.in/

2. **Telemedicine Practice Guidelines, 2020**

   Issued jointly by the Ministry of Health and Family Welfare and the Board of Governors in supersession of the Medical Council of India, these guidelines aim to formalize the practice of telemedicine in India. While they acknowledge the auxiliary role of AI tools in assisting practitioners, they explicitly prohibit AI from making autonomous decisions in diagnosis or treatment. The physician remains fully responsible for any clinical decision, highlighting the limited trust placed in AI without human oversight (MoHFW, 2020).

3. **Personal Data Protection Bill, 2019 (now replaced by the Digital Personal Data Protection Act, 2023)**

   The PDP Bill, and its successor, the Digital Personal Data Protection Act, 2023, provide a legal framework for the handling of personal data, including health data. These legislations emphasize consent, data minimization, and purpose limitation. However, they remain broad and do not address the nuances of health-specific AI applications—such as the right to explanation for automated decisions or the anonymization of training datasets used by AI systems (MeitY, 2023).

4. **Medical Device Rules, 2017**

   The 2017 Rules categorize certain software intended for diagnosis or treatment under the "Software as a Medical Device" (SaMD) framework. While in theory, AI tools for clinical use fall under this category, in practice, there is significant ambiguity around whether all AI-based products are being regulated accordingly. There is also no standard for clinical validation, calibration, or approval of adaptive or self-learning algorithms, leading to regulatory uncertainty (CDSCO, 2017).

IDENTIFIED REGULATORY GAPS

- **Absence of Dedicated AI Legislation**: There is no overarching law that addresses the development, deployment, validation, and governance of AI in healthcare.

- **No Standards for Algorithmic Bias and Fairness**: Current frameworks do not mandate audits or testing for bias in AI models, which can have real-world implications for diagnosis across demographic groups.

- **Unclear Certification and Liability Mechanisms**: While some AI tools may qualify as medical devices, there is no streamlined pathway for certification, and liability for AI errors remains undefined.

- **Lack of Ethical Oversight**: Unlike clinical drug trials, AI systems are not subject to review by ethics committees, leaving a gap in oversight for issues like consent, privacy, and autonomy.

In essence, the absence of a harmonized and sector-specific regulatory framework for AI in healthcare has led to a situation where innovation continues unchecked by legal standards, posing potential risks to patient safety, data privacy, and the overall integrity of medical care.

***Regulatory Gaps**:*

- **No mandatory clinical validation**: Many AI systems used in diagnosis are not validated for accuracy and safety by an Indian regulatory authority.

- **Lack of standardization**: No clear standards for training data, algorithm bias testing, or interpretability of AI models.

- **Absence of liability guidelines**: In case of AI error, it's unclear who is liable—the developer, the hospital, or the healthcare provider.

- **No ethical oversight**: No institutional ethics board exists to review AI models in healthcare the way human trials are reviewed.[2]

These gaps can lead to misuse, errors in medical decisions, and erosion of patient trust.

COMPARATIVE GLOBAL FRAMEWORKS AND LESSONS FOR INDIA

Several countries have initiated robust frameworks to regulate AI in healthcare, which India can learn from.

United States: The U.S. Food and Drug Administration (FDA) classifies AI-based medical software under its SaMD (Software as a Medical Device) framework. It evaluates safety, efficacy, and post-market surveillance. The FDA has also published action

[2] The *Telemedicine Practice Guidelines* (2020) restrict AI from independently making clinical decisions, requiring human oversight at all stages (MoHFW, 2020).

plans specifically for AI/ML-based devices, emphasizing continuous learning systems and real-world performance monitoring.

European Union: The EU's Artificial Intelligence Act classifies AI systems by risk category—"high-risk" AI (including healthcare tools) must meet strict requirements related to transparency, accountability, and data governance.

United Kingdom: The UK's MHRA (Medicines and Healthcare Products Regulatory Agency) is working on a multi-stakeholder framework to regulate adaptive AI in medical tools. The NHS also has a Code of Conduct for Data-Driven Health Technologies.

China: China has issued specific guidelines for AI in healthcare, requiring products to pass a registration process with the National Medical Products Administration (NMPA) and emphasizing data localization.[3]

Key lessons for India:

- Adopt a risk-based framework for AI classification.
- Require clinical validation and certification for AI-based tools.
- Establish an independent regulatory body or strengthen the CDSCO's role.
- Enforce clear data protection and consent mechanisms.

RECOMMENDATIONS AND CONCLUSION

To ensure that AI in healthcare delivers on its promise without compromising safety or ethics, India must build a robust and responsive regulatory framework. Some recommended steps include:

1. Formulate a dedicated AI in Healthcare Regulation

- A unified law or guidelines from the Ministry of Health in consultation with NITI Aayog, ICMR, and CDSCO should regulate AI-based medical devices.
- Regulations should mandate risk classification, clinical trials, and ethical audits.

[3] National Medical Products Administration (NMPA), China. (2021). *AI Medical Device Registration Guidelines* (translated summaries via MedTech).

2. Mandate Clinical Validation

- All AI tools intended for diagnostic or therapeutic use must undergo rigorous testing for accuracy, sensitivity, and generalizability across different Indian populations.

3. Establish an AI Ethics Board

- Similar to Institutional Ethics Committees for drug trials, AI projects in healthcare must be reviewed for fairness, transparency, and informed consent.

4. Strengthen Data Protection Laws

- With health data being sensitive, the Digital Personal Data Protection Act must be enforced strictly, with special rules for healthcare AI.

5. Accountability and Redress Mechanisms

- Clearly define legal liability in cases of AI errors. Encourage insurance coverage and accountability protocols for AI developers and users.

6. Promote Interdisciplinary Research

- Encourage collaboration between technologists, healthcare professionals, legal experts, and ethicists to build socially responsible AI.

CONCLUSION

India stands at a critical juncture where AI can dramatically improve healthcare access and quality. However, without a robust regulatory framework, it also poses serious ethical and safety risks. Learning from global models and tailoring regulations to India's unique challenges can ensure that AI becomes a force for good in Indian healthcare—one that is inclusive, transparent, and safe. The time to act is now, to strike a balance between innovation and regulation.

REFERENCES

- NITI Aayog. (2018). *National Strategy for Artificial Intelligence*. Government of India. https://www.niti.gov.in/
- Ministry of Health and Family Welfare. (2020). *Telemedicine Practice Guidelines*. https://www.mohfw.gov.in/

- Central Drugs Standard Control Organization (CDSCO). (2017). *Medical Devices Rules, 2017*. https://cdsco.gov.in/
- Ministry of Electronics and Information Technology. (2023). *Digital Personal Data Protection Act*. Government of India. https://www.meity.gov.in/
- Food and Drug Administration (FDA), U.S. (2021). *Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device Action Plan*. https://www.fda.gov/media/145022/download

- European Commission. (2021). *Proposal for a Regulation Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act)*. https://eur-lex.europa.eu/