

# A Study of Legal Regulation of Telemedicine in India

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## Abstract

Healthcare is most essential for human beings that means it must be easily accessible, affordable, available for all the people. However, high number of populations of India which is continuously growing, is causing heavy burden on the healthcare institutions (especially public healthcare institutions). Due to which it is getting difficult to ensure all 3 A's (accessibility, affordability, and availability) for the people.

Telemedicine practice which got popularity during COVID pandemic comes as boon. It utilises information and communication technological tools to facilitate virtual doctor-patient interaction whereby doctor seeks to understand about the symptoms and medical history of the patient based upon that he recommends certain investigations and further proceeds to provide knowledge, counselling, and in certain needful cases prescription for medications.

Prior to pandemic there was huge misunderstanding regarding regulation and proper procedure to be followed in practice of telemedicine. Then came Telemedicine Practice Guidelines 2020 determining rights and duties for both the medical professionals and intermediaries providing platforms facilitating telemedicine practice. The authors in this paper attempts to understand practice of telemedicine and challenges for this to grow along with concerns surrounding delivery of quality healthcare services.

**Keywords:** Telemedicine, Coronavirus, Consent, Privacy, Population.

## Introduction

The day started with newspaper headlines about the spread of Coronavirus, and that evening ended with the lockdown. In such a time when people had nowhere to go, telemedicine came to their rescue. They could reach qualified doctors using online platforms that provide healthcare consultation services online. In which, a doctor after doing detailed evaluation about the medical history and symptoms, prescribes medicines and recommends all the necessary measures to be taken. This way, telemedicine saved the lives of many individuals who were in dire need of medical support in the unprecedented times of lockdown.

Though the term 'telemedicine' was coined in the 1970s, it has gained popularity in recent times, especially during the COVID-19 outbreak. Since then, the practice of telemedicine has grown rapidly across the Country and proved a boon for the mankind. The Indian Telemedicine Market grew from \$830 million in FY2019<sup>3</sup> to \$1314.83 million in FY2021 and is expected to grow at a robust CAGR of around

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<sup>3</sup> Indian Telemedicine Market Analysis, Insight10, available at: <https://insights10.com/product/india-telemedicine-market-analysis/> (last visited on December 05, 2024).

22.31%.<sup>4</sup> At the same time, it has also raised certain concerns about deficiency in healthcare services, resulting in medical negligence.

In present times, the hospitals are already overburdened, especially the public sector hospitals. This burden is also on the rise in proportion to the rapidly increasing population of the Country. Therefore, the growth of the telemedicine industry is undoubtedly a boon for the patients and healthcare professionals as well. It is helpful in reducing the burden of non-serious patients at hospitals and the costs of healthcare expenditure. However, such growth in the practice of telemedicine emphasizes its effective regulation. Otherwise, it may give rise to various unethical and corrupt practices.

The authors herein this paper attempt to understand the practice of telemedicine in light of the requisite standards and further look for solutions in case any wrongful acts or omissions occur during the practice of telemedicine. The authors utilize doctrinal methods for the collection of data to enquire into the relevant position of telemedicine in India through the study of regulatory guidelines and various articles on the concerned issue.

### Telemedicine: An Introduction

The term ‘telemedicine’ was taken from the Greek word ‘tele’ which means ‘distance’ and the Latin word ‘mederi’ which means ‘to heal.’<sup>5</sup> Telemedicine is the use of Information and Communication Technologies (ICT) to overcome challenges posed by distance in providing accessible, cost-effective, timely and high-quality healthcare services by enabling appointments via phone, video calls, etc., between patients and their doctors.<sup>6</sup> It has a variety of applications in patient care, education, research, administration and public health.<sup>7</sup>

The WHO defined telemedicine as-

*“The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities.”<sup>8</sup>*

Generally, people living in remote areas, especially rural India, fail to get proper medical care from specialist medical professionals, who are usually based far in large urban areas, like metropolitan cities. This factor gives birth to the inability of such people to reach there in due time and receive effective healthcare services. Along with the availability-related factor, other factors of affordability and accessibility also play a crucial role because getting access to the super specialty healthcare services at public healthcare institutions is very difficult due to their already overburdened healthcare facilities,

<sup>4</sup> Research and Markets, “India Telemedicine Market Report 2021” *PR Newswire*, Oct. 08, 2021, available at: <https://www.prnewswire.com/news-releases/india-telemedicine-market-report-2021-301396123.html> (last visited on December 02, 2024).

<sup>5</sup> Aparajita Dasgupta and Soumya Deb, “Telemedicine: A New Horizon in Public Health in India” 33(1) *Indian Journal of Community Medicine* 3–8 (2008), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2782224/#:~:text=Telemedicine%20is%20the%20use%20of,word%20meaning%20E2%80%9Cto%20heal%20E2%80%9D> (last visited on January 01, 2025).

<sup>6</sup> The WHO, “Telemedicine: Opportunities and Developments in Member States: Report on Second Global Survey on e-Health” (2010), available at: [https://iris.who.int/bitstream/handle/10665/44497/9789241564144\\_eng.pdf?sequence=1&isAllowed=y](https://iris.who.int/bitstream/handle/10665/44497/9789241564144_eng.pdf?sequence=1&isAllowed=y) (last visited on December 23, 2024).

<sup>7</sup> *Supra* note 5.

<sup>8</sup> *Supra* note 6.

whereas the question of affordability comes into the picture at private healthcare institutions where healthcare expenditure is very high. Therefore, to address such issues and penetrate effective healthcare services deeper into the remote areas of India, telemedicine is playing a very crucial role in bridging the gap.

### **Significance of Telemedicine in India**

India is the country with the highest number of the population share in the world, with approximately 145 Cr.<sup>9</sup> Of this large population, only about 37.1% is urban, and the rest, about 62.9% of the population is rural.<sup>10</sup> Herein India, all the good doctors (especially specialist doctors) are found in urban areas, mostly in metropolitan cities. This makes the majority of the Indian population deprived of timely medical support to meet the needs of time. People belonging to rural areas and semi-urban areas have to spend a few to several hours to get access to necessary healthcare support. The practice of telemedicine can help smoothen over such inequalities by enabling easy access to effective healthcare support in due time. Based upon the preliminary inquiry, the doctor can advise a remedy if the healthcare concern is minor or can advise some immediate measures so that the person can safely reach the nearby full-support healthcare institution.

Another factor is that the hospitals (especially public hospitals) in India are highly overburdened. This burden includes both serious and non-serious patients. Promoting telemedicine can help reduce the number of non-serious patients on the hospital premises, thereby giving better opportunities for doctors to pay attention to serious patients.

### **The Practice of Telemedicine**

The practice of telemedicine is performed by using two ways- the first being the 'store and forward' method in which data regarding a patient's health is communicated in the form of text, images, and videos to the concerned medical professional who, after assessing the data, form a professional judgment about the case. Based on this, he provides a prescription recommending specific remedies in the next few hours. On the other hand, the second method consists of a 'one-to-one real-time interactive session' wherein both the patient and the medical professional come face to face and share information during their live interaction through video conferencing, phone calls, etc.<sup>11</sup>

Telemedicine is one of the revolutionary tools that utilizes the modern technological resources to boost growth in the healthcare sector. But like many other scientific developments, it also does not come free from shortcomings. Thus, it raises doubts regarding the efficiency and efficacy of Information and Communication Technology (ICT) and its role in the healthcare domain. The system of telemedicine may act as an effective medium only when technology enables accurate data capture, recording and transferring of information, etc. while maintaining privacy in such communications.

### **Challenges for the Practice of Telemedicine**

The challenges being faced by telemedicine in India are as given below-

1. The insufficient training to effectively conduct triage and make timely and accurate diagnoses as req-

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<sup>9</sup> India Population, Worldometer, *available at*: <https://www.worldometers.info/world-population/india-population/> (last visited on January 14, 2025).

<sup>10</sup> *Ibid.*

<sup>11</sup> *Supra* note 5.

uired;

2. Patient data, health records, and medical histories require adequate infrastructure and storage space, creating the need for a proper technical infrastructure and data storage system;
3. The lack of digital literacy among half the population, especially in rural areas, hinders the effective use of telemedicine;
4. Connectivity, infrastructure, and technical support also present significant challenges;
5. The guidelines do not outline data privacy or security requirements except for obtaining the patient's consent;
6. The complexity of a patient's health condition may vary, but the registered medical practitioner (RMP) is required to maintain the same standard of care as in an in-person consultation while operating within the inherent limitations of telemedicine;
7. The low digital literacy rate in India also poses challenges in identifying registered medical practitioners, as telemedicine consultations should not be anonymous; both the patient and the RMP must be aware of each other's identity.<sup>12</sup>

### Regulation of Telemedicine in India

Prior to 2020, the position of patients was very vague concerning the use of telemedicine, which got changed after the advent of the Telemedicine Practice Guidelines in March 2020. However, there was a case in which the Bombay High Court denied anticipatory bail to two doctors for negligence in treatment because of which she died, and in response, her husband filed a case of criminal negligence against the doctors.<sup>13</sup> This was a case of telemedicine as telecommunication mode was applied for consultation purposes.<sup>14</sup>

In the year 2019, the National Medical Commission replaced the erstwhile Medical Council of India, setting a new era for the regulation of the medical profession, medical education, and medical institutions, etc. The National Medical Commission got established under the provisions of the National Medical Commission Act 2019 (Hereinafter referred to as NMC Act). Exercising the powers given under section 57 of the NMC Act the Commission brought in regulations namely "National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2023" to regulate medical professional conduct, aspects of medical practice, prescribing ethical standards etc. These regulations replaced the earlier Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002. The new Regulations 2023 also contained "Guidelines for the Practice of Telemedicine in India". Though the new Regulations of 2023 were notified in the gazette but faced several objections from the side of medical professionals and pharmaceutical associations, following which the NMC put such Regulations of 2023 on hold and again old regime of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 came into effect for the time being till the renotification of

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<sup>12</sup> Board of Governors, "Telemedicine Practice Guidelines: Enabling Registered Medical Practitioners to Provide Healthcare Using Telemedicine" (March 2020), available at: <https://www.mohfw.gov.in/pdf/Telemedicine.pdf> (last visited on December 25, 2024).

<sup>13</sup> *Deepa Sanjeev Pawaskar v. State of Maharashtra* 2018(4)BomCR(Cri.)261.

<sup>14</sup> Aishani Singh, "Telemedicine & Law— An Indian Perspective" *IIPRD Blog*, available at: [https://iiprd.wordpress.com/2020/05/13/telemedicine-law-an-indian-perspective/?utm\\_source=Mondaq&utm\\_medium=syndication&utm\\_campaign=LinkedIn-integration](https://iiprd.wordpress.com/2020/05/13/telemedicine-law-an-indian-perspective/?utm_source=Mondaq&utm_medium=syndication&utm_campaign=LinkedIn-integration) (last visited on January 03, 2025).

Regulation of 2023 in the gazette. Similarly, the Telemedicine Practice Guidelines of 2020 again went into effect to regulate the practice of telemedicine in India.

In the realm of telemedicine for breach of duty, two kinds of liabilities come into the picture- the first being the vicarious liability of telemedicine service providers and the other being the liability of the intermediaries. Though these two liabilities are of different origins, they are very closely associated with respect to the telemedicine sector. Here, on one hand, while the telemedicine platform has the right, liability, and duty to control the activities of the wrongdoer and fails to do so, he is made vicariously liable. On the other hand, his liabilities as an intermediary arise when he facilitates and attempts to hide the wrongdoers' actions. The vicarious liability in this case is dealt with mainly by the Consumer Protection Act of 2019, while intermediary liability is derived from the Information Technology Act of 2000.<sup>15</sup>

Regarding vicarious liability, it is generally misunderstood that telemedicine platforms merely provide an infrastructure where a medical professional is running his professional services. It is often argued that, in present times, various platforms are emerging as modern marketplaces where anyone can register themselves to provide their services. In such cases, a master-servant relationship is absent when employing doctors; therefore, they cannot be held vicariously liable. Furthermore, the platforms argue that they are only facilitators of infrastructure for doctor's consultation services rather than directly giving medical advice to the patients. Thus, they are free from any sort of liability arising out of the doctor-patient relationship, i.e., deficiency in service or not meeting the regulatory standards, etc.

Such arguments lose any worth by effect of the telemedicine guidelines of 2020 as it clearly states that registered medical practitioners (hereinafter referred to as RMPs) practicing telemedicine shall have to work in accordance with the same professional and ethical norms and standards as are applicable to traditional in-person care, within the intrinsic limitations of telemedicine.<sup>16</sup> In accordance with the guidelines, like in the traditional mode of consultation, in telemedicine, the consent of the patient is the primary requirement, but it must be informed consent. It may be obtained explicitly or impliedly, depending upon the initiation of telemedicine consultation.<sup>17</sup> Similarly, as all the patients accessing telemedicine will require different types of treatment, the RMP will have to ascertain appropriate diagnosis based upon which they will form their professional judgment<sup>18</sup> and provide necessary healthcare recommendations,<sup>19</sup> following the same standard of care that they would have taken during an in-person consultation.<sup>20</sup> This reflects the intention of the framers of guidelines that the liability for medical negligence or professional misconduct should *ejusdem generis* be applied in cases of telemedicine too.

Such arguments had also been raised by the hospitals that they are merely a facilitator of infrastructure and merely provide support staff. Therefore, they are not vicariously liable for deficiency in healthcare services. The SC in the case of *Smt. Savita Garg vs. The Director, National Heart Institute*, observed that when patients go to hospitals by their reputation and have an expectation of proper care by the hospital

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<sup>15</sup> Arogya Legal, "The Liability Conundrum for Telemedicine Platforms in India: Striking a Balance between Vicarious and Intermediary Liability" *Arogya Legal*, July 27, 2021, available at: <https://arogyalegal.com/2021/article/the-liability-conundrum-for-telemedicine-platforms-in-india-striking-a-balance-between-vicarious-and-intermediary-liability/> (last visited on January 05, 2025).

<sup>16</sup> Telemedicine Practice Guidelines: Enabling Registered Medical Practitioners to Provide Healthcare Using Telemedicine 2020, 1.3.2, available at: [https://esanjeevani.mohfw.gov.in/assets/guidelines/Telemedicine\\_Practice\\_Guidelines.pdf](https://esanjeevani.mohfw.gov.in/assets/guidelines/Telemedicine_Practice_Guidelines.pdf) (last visited on December 10, 2024).

<sup>17</sup> *Id.* at 3.4.1.

<sup>18</sup> *Id.* at 3.7.1.

<sup>19</sup> *Id.* at 3.7.2.

<sup>20</sup> *Id.* at 3.7.4.

authority, they agree to pay the requisite fees as charged by hospitals for their services (medical as well as non-medical services). Therefore, they are duty-bound towards that patient.<sup>21</sup> The National Consumer Disputes Redressal Commission (NCDRC) has also, in the case of *Smt. Rekha Gupta v. Bombay Hospital Trust*<sup>22</sup> pointed out that the bills for doctor's consultations are raised by the hospital and they charge a commission before remitting the fee to the consultant. Therefore, they cannot escape their liability.

The application of this reasoning by which courts hold hospitals vicariously liable would logically be applicable to holding telemedicine platforms liable as well. This way it is thus unlikely that they would be eligible for a blanket exemption from liability for negligence or deficiency in services offered through the platform by claiming that they are merely technology providers that do not play a role in the actual rendering of medical services.<sup>23</sup>

Hereby, the telemedicine platforms are liable as a hospital; at the same time, they also have certain safeguards for themselves. They can reduce the risk of them being held liable by undertaking due diligence and adopting appropriate measures in accordance with the prescribed standards. In other words, a telemedicine platform must ensure that the person providing services through their platform is a well-qualified registered medical practitioner.<sup>24</sup> They should verify all the necessary documents in this regard. The platforms should ensure that the RMP is well-versed in practical, technical, and legal issues relating to telemedicine and properly complies with the platform's policies. They have to ensure that the name, qualification, contact details of the RMP and other necessary details are displayed on the platform<sup>25</sup> and if the RMP doesn't abide by it, they are required to report to the Board of Governors, who will take necessary action in this regard.<sup>26</sup> In order to address other issues where liability can arise, is service delivery should ensure the best possible delivery of quality service, protection of patients' data, smooth interaction between doctors and patients, etc.

After proper investigation of the patient the doctor forms his opinion about the health condition of the patient and based upon that he may impart health-related education to the patient i.e., diet to be followed, kind of exercise to be done, cessation of smoking or any sorts of drugs, or precautions to be taken in case of particular situations;<sup>27</sup> do counselling of the patient, which will contain specific advice regarding any particular ongoing health condition, any sort of do's or don'ts while taking specific medicines, or further investigations and possible occurrences in the future.<sup>28</sup> In telemedicine consultations, the registered medical practitioner may prescribe medicines but only after being fully satisfied with the particular health condition of the patient because failing to meet this requirement amounts to professional misconduct.<sup>29</sup> The RMP, in the teleconsultation process, shall prescribe medicines subject to certain restrictions that depend upon the mode and type of consultation. The medicines that can be prescribed in the teleconsultation process have been categorized into List O, List A, List B and Prohibited List. Of these List O contains ordinary medicines which are also known as 'over-the-counter drugs' i.e. paracetamol, ORS, cough lozenges etc., these are safe to be prescribed in any mode of consultation. List A drugs are

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<sup>21</sup> *Supra* note 15.

<sup>22</sup> *Smt. Rekha Gupta v. Bombay Hospital Trust* II(2003)CPJ160NC.

<sup>23</sup> *Supra* note 15.

<sup>24</sup> *Supra* note 16 at 5.1.

<sup>25</sup> *Id.* at 5.2.

<sup>26</sup> *Id.* at 5.3.

<sup>27</sup> *Id.* at 3.7.2.

<sup>28</sup> *Id.* at 3.7.3.

<sup>29</sup> *Id.* at 3.7.4.

those which are also safer from the point of any abuse and need to be prescribed, especially in first-time consultation in video conferencing mode and further for re-fill purposes in follow-up consultations. Next is list B, which contains medicines that are to be prescribed in follow-up consultations along with ongoing medicines. Lastly, the prohibited list cannot be prescribed for being dangerous for the patient and society at large, if used improperly.<sup>30</sup>

## Conclusion

Telemedicine is a revolutionary step in the field of healthcare services. Bringing a mode for the provision of healthcare services online from the traditional in-person approach by utilizing various technological advancements and tools of present times can solve many problems which the healthcare system itself and common people are going through every day i.e., overcrowding of healthcare institutions hampering interests of both medical professionals, non-medical staff and patients; also inconvenience of visiting hospitals even for minor issues. In teleconsultation hassle-free consultation can be done from the convenience of home. While it is so beneficial to use telemedicine, it also raises concerns regarding quality of care. Though the telemedicine practice guidelines cover such issues and provide solutions to remedy those, the patient has to always be aware of his health and, if necessary, approach in-person consultation, which is necessary. The medical professionals practicing telemedicine and telemedicine platforms also need to always abide by the regulatory guidelines in order to ensure the provision of quality healthcare services.

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<sup>30</sup> *Id.* at 3.7.4.