

TELEMEDICINE: - A STUDY OF REGULATORY FRAMEWORK IN INDIA

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ABSTRACT

Telemedicine is the practice of using various means of telecommunication technologies to conduct remote diagnosis treatment and consultation by healthcare professionals. In India Telemedicine can be the answer to providing access to substantial healthcare solutions in underdeveloped and low-income regions. Although Telemedicine in India is still in its nascent stages with multiple growing start-ups providing healthcare solutions through various telemedicine platforms and the government bringing in multiple policy regulations in the past 3-4 years field still has the potential to grow exponentially. This article explores all the current legislation and guidelines in force around the Telemedicine sector.

Keywords- Telemedicine, Healthcare, Covid-19, IT Regulations, Data Protection

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INTRODUCTION

Internet access and online infrastructure in India have experienced an exponential boost over the past few years. Internet access today has an increased penetration across the country, allowing for e commerce platforms to expand their market base from Tier-I cities and move into smaller towns and even villages, areas which were previously dominated by traditional brick and mortar stores.

With an active user base of over 624 million daily internet users and growing¹, and e commerce having an active penetration of 76.7% in the country, opportunities in this sector are endless. E commerce is set to become a 73-billion-dollar industry by 2022 in India.

Telemedicine is one such sector of this E-Commerce industry, which has seen a huge boost in recent times. India has adopted the WHO definition of Telemedicine, which is as follows; “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”

Telemedicine holds promise to expand people's access to high-quality healthcare across the country. Telemedicine holds promise to expand people's access to high-quality healthcare across the country. WHO prescribes for a 1:1000 Doctor/Patient Ratio as an ideal standard. This means one doctor for every 1000 patients. India has a population of 1.3 billion people and according to the data published by the 15th Finance Commission in 2021; our ratio is 0.66 doctors for every 1000 people². Even within this ratio, the dispersion of practicing Healthcare Professionals is widely skewed between urban and rural areas, with most of the professionals preferring to work in urban areas over rural areas. This has led to a situation where multiple states in India such as Tamil Nadu, Punjab having a ratio well above the WHO prescribed norms, while states like Chhattisgarh, Uttar Pradesh and Bihar lag behind. Telemedicine can

¹ Total internet users in India | Statista, Statista (2021), <https://www.statista.com/statistics/255146/number-of-internet-users-in-india/> (last visited Dec 11, 2021).

² A Report of high level group on Health Sector submitted to the Fifteenth Finance Commission of India, https://fincomindia.nic.in/writereaddata/html_en_files/fincom15/StudyReports/High%20Level%20group%20of%20Health%20Sector.pdf (last visited Dec 11, 2021)

assist in overcoming these barriers by allowing doctors in urban areas to deliver consultations and specialised care to patients in rural areas as needed.

The Covid outbreak in the country has also highlighted the poor state of the Indian healthcare infrastructure. Hospitals were overwhelmed with patients and the system almost collapsed under the pressure. Along-with much needed investment and reforms healthcare sector, telemedicine can act as the perfect support system in these times of need. Healthcare practitioners can provide remote consultations to those patients who are not in non-emergency situations, allowing for a more efficient management of patients. This would also reduce the risk of transmission to healthy individuals from hospitals by reducing the need for visits at every stage.

How Telemedicine is Changing Healthcare

According to a World Health Organization study, 59.2% of all health workers work in cities, which account for 27.8% of the population, and 40.8 percent work in rural areas, which account for 72.2 percent of the population.³

This is where telemedicine may help. You may obtain 24/7 diagnosis and treatment from the comfort of your own home instead of scheduling an in-person visit for non-emergency injuries or illnesses. Minor ailments can be treated via remote consultations before they become big problems. This can save both patients and healthcare providers a significant amount of time.

Telemedicine may also link you with specialists, which is especially useful if you have restricted access to transportation or healthcare facilities. Because they do not have to travel, these specialists can give care to patients even in rural regions.

Intel is working with Medical Informatics Corporation (MIC) to develop systems that will help hospitals centralise and analyse data from devices that monitor patients' vital signs, reducing the number of rounds care teams must make and "alarm fatigue" by triaging the patients to whom they must respond.⁴

³ Sudhir Anand and Victoria Fam, THE HEALTH WORKFORCE IN INDIA,WHO, https://www.who.int/hrh/resources/16058health_workforce_India.pdf (last visited Dec 11, 2021)

⁴ Insights Team, Forbes Insights: How Telemedicine Is Transforming Healthcare: How AI And Edge Are Shaping The Future Forbes (2021), <https://www.forbes.com/sites/insights-inteliot/2020/12/03/how-telemedicine-is-transforming-healthcare-how-ai-and-edge-are-shaping-the-future/?sh=1e525f753e4e> (last visited Dec 11, 2021).

Secure cabling, high-resolution cameras, speakers, and monitors may need to be installed in hospitals, clinics, nursing homes, and physicians' offices. The future of telemedicine will equip health facilities to serve as distant care centres.

This extraordinary increase in teleconsultations, telepathology, teleradiology, and e-pharmacies is anticipated to drive the Indian telemedicine industry to \$5.5 billion by 2025.⁵ In India, start-ups such as Phable, Practo, mFine, CallHealth, and Lybrate are launching new telemedicine platforms. Telemedicine has meant that Doctors and medical personnel can more efficiently prioritize critical situations. Human error and delays can be eliminated as well. More financing and investment in the industry are projected as a result of the government's support, eventually improving the country's place on the global healthcare map.

With increasing digital penetration in India, the rise of telemedicine as an antidote to public health gaps is likely to be one of the pandemic's significant findings.

Regulatory framework governing telemedicine

The following laws and guidelines regulate the practice of telemedicine in India

1. National Medical Commission Act, 2019: -⁶

In September 2020, the Ministry of Health and Welfare declared the NMC Act to be the fundamental law governing medical education and practise in India. It took the place of the Indian Medical Council Act, 1956, which had previously been in force. The new law states that the rules and regulations framed asunder the old act will still apply and remain in force as a transition mechanism until new guidelines are notified under the present act. The MCI code which establishes the professional and ethical norms that doctors must adhere to when dealing with patients and pharmaceutical corporations. still remains in force and will continue to do so until new guidelines are set under the present law.

2. Telemedicine Practice Guidelines: -⁷

⁵ Telemedicine market in India to reach USD 5.5 billion by 2025: EY-IPA study, The Economic Times (2021), <https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/telemedicine-market-in-india-to-reach-usd-5-5-billion-by-2025-ey-ipa-study/articleshow/77996931.cms?from=mdr> (last visited Dec 11, 2021).

⁶ National Medical Commission Act, 2019; <https://egazette.nic.in/WriteReadData/2019/210357.pdf>

⁷ Telemedicine Practice Guidelines ;<https://www.mohfw.gov.in/pdf/Telemedicine.pdf>

Issued by The Ministry of Health and Welfare in collaboration with the NITI Aayog; these guidelines form a part of the existing ethics code. The goal of these recommendations is to provide doctors with practical guidance so that all services and models of care utilised by doctors and health professionals may embrace telemedicine as a part of standard practise. These standard operating procedures are binding on all doctors practicing allopathy and enable them to use telemedicine platforms in any part of the country. The guidelines have categorically explained over what kind of consultation and care may be provided by doctors while engaging over telemedicine platforms and in what manner such care and consultation may be provided. For example, the guidelines have classified various medicines in List B, List A, List O and Prohibited Category; allowing for a clear distinction between different medicines and outlining which kinds of drugs can be prescribed over the platform and in which conditions.

3. Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945: -⁸

The act and the rules established through this act aim to regulate the import, manufacture sale and distribution of drugs and cosmetics in India. The definition of a "drug" is found in Section 3(b) of the act. To sell any kind of drug in India except certain drugs intended for non-medical use or certain malaria-curing drugs, a License is required and no distinction is made between drugs which may be sold exclusively on the prescription given by a physician and drugs which may be brought over the counter. However, the Rules made through this act form a clear distinction between prescription and non-prescription drugs. Schedules H, H1, and X of the D&C Rules detail the medications that can only be purchased with a prescription.

Even the drugs sold over telemedicine platform on the basis of a prescription must satisfy all legal requirements. A legitimate prescription is one that has been written, signed, and dated by the doctor who is writing it. The prescription must also provide the quantity of the prescription suggested by the doctor and the name and the address of the patient who is getting the treatment.

⁸Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945;
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf

Certain drugs and cosmetic are completely prohibited to be sold over telemedicine platforms. The Drugs and Cosmetics Act, 1940 for example, prohibits Anti-Cancer drugs from being prescribed over telemedicine platforms.

4. The Information Technology Act, 2000⁹, The Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011¹⁰ (Data Protection Rules) and the Information Technology Rules, 2011 (Intermediary Guidelines)¹¹: -

As internet access permeates deeper within the Indian Society and traditional brick and mortar stores too start to go online, a huge chunk of information and data is being transferred in the digital space; data which normally would've remained only on paper and confidential between the customer and service provider. This raises significant issues of privacy and fundamental rights.

Same is true for the Telemedicine sector. Under the Data Protection Rules, a Patient's personal information that he provides on such sites is considered Sensitive Personal Data. When a corporate entity such as a telemedicine service providing platform collects, stores, transfers or processes such information; these Data protection Rules are prompted. The Data Protection Rules are formed on the cornerstone of consent of the consumer; and require entities such as telemedicine providers to obtain consent while transferring and or collecting Sensitive Personal Data Information. They are also required to inform the end user of such collected data. They also require such corporate entities to have a robust privacy policy and to ensure the security of data of the end user.

5. Telecom Commercial Communication Customer Preference Regulations, 2018¹²:-

⁹The Information Technology Act, 2000;<https://eprocure.gov.in/cppp/rulesandprocs/kbadqkdlcswfjdelrquehwuxcfmijmuixngudufgbuubgubfugbubu b jxcgfv sbdihbgfGhd fgFHytyhRtMjk4NzY=>

¹⁰ The Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011;https://www.meity.gov.in/writereaddata/files/GSR313E_10511%281%29_0.pdf

¹¹ (Data Protection Rules) and the Information Technology Rules, 2011 (Intermediary Guidelines) https://www.meity.gov.in/writereaddata/files/Draft_Intermediary_Amendment_24122018.pdf

¹² Telecom Commercial Communication Customer Preference Regulations, 2018;<https://traf.gov.in/sites/default/files/RegulationUcc19072018.pdf>

Apart from the interaction over the platform, Healthcare practitioners may have to interact with the patients through other means such as SMS or the platform itself may end up interacting with the user through promotional messages/offers/follow up reminders etc. Actions of the Telemedicine platform in which they engage with the Healthcare providers and end user in terms of promotional, marketing and transactional messages being sent are governed by these regulations.

6. OSP Regulations under the New Telecom Policy, 1999¹³: -

The Department of Telecommunication requires service providers who render “Application Services” and use telecom resources provided by Telecom Service Providers to be registered as Other Service Providers. Service Providers have to obtain a license before providing such services and have to comply with certain regulatory norms and requirements to be granted such license.

Telemedicine Practice Guidelines: -

The Covid-19 pandemic, forced a lot of business entities to start work from home and to go online. Telemedicine also saw a significant rise as lockdown restrictions became more forceful and going out became much more dangerous. In light of these events, the government issued these guidelines to healthcare practitioners in March 2020 to guide them on the usage of telemedicine amidst the growing pandemic. These guidelines act in supplement to the existing laws mentioned above and have helped to plug in the gaps which were present earlier. The purpose of these guidelines is to assist medical practitioners in developing a sound plan of action for providing effective and safe medical treatment based on available information, resources at hand, and needs of the patient, in order to protect both patients and providers.

Only Healthcare Practitioners who practise allopathy and are registered with a state medical council come under the ambit of Telemedicine Practice Guidelines. Dentists and practitioner of other forms of medicine e.g., Ayurveda, Homeopathy and Siddhi medicine are not covered by these Guidelines. The Central Council for Indian Medicine has released a separate set of standard operating procedures for doctors who practice other traditional forms of Indian Medicine such as Ayurveda, Siddha and Unani forms of medicine and the Central Council for Homeopathy has released a separate set of guidelines for homeopathy practitioners as well.

¹³ OSP Regulations under the New Telecom Policy, 1999; <https://dot.gov.in/new-telecom-policy-1999>

However, these principles do not apply to other telemedicine stakeholders such as patients, telemedicine platforms, messaging apps, insurance providers, and other entities in the ecosystem. However, if Telemedicine platforms were to get proactive and comply with these guidelines, it would help in encouraging Registered Medical practitioners to consult over a platform which complies with all legal norms rather than the one which does not.

The Bombay High Court's judgement in the case of *Deepa Sanjeev Pawaskar and Anr vs The State of Maharashtra*¹⁴ in 2018 sparked questions among RMPs about whether they may provide medical advice over the phone. The Bombay High Court refused the applicant's (Dr. Deepa's) anticipatory bail application, noting her arrest under Section 304 of the Indian Penal Code, 1860 (culpable homicide). While the Supreme Court overruled the Bombay High Court's ruling, many RMPs in India remained leery about giving medical advice over the phone.

According to the TPG, the RMP shall use their professional judgement to determine if telemedicine is an appropriate sort of consultation. The factors listed in the guidelines should be considered when deciding whether or not to consult via telemedicine. The TPG also specifies which medications may be prescribed and under what circumstances.

Depending on whether the teleconsultation was started by the patient, caregiver, or RMP, the technique utilised to get patient consent as outlined in the recommendations varies. If the patient initiates the teleconsultation, the patient's agreement is implied. The patient's explicit agreement should be documented if the teleconsultation is initiated by the caregiver, health worker, or RMP. An email, text message, or audio/video message could be used to keep track of the information.

Platform Guidelines

The Telemedicine Practice Guidelines also provide guidelines that are to be followed by Telemedicine platforms. Technology platforms that provide telemedicine services must ensure that patients consult with a registered medical practitioner and must undertake due diligence before putting any practitioner on their web portal. Every qualified medical practitioner featured on the platform must have a name, qualification, and registration number, as well as contact information. Any misbehaviour or noncompliance by the practitioner must be reported to the appropriate authorities.

¹⁴ 2018 SCC OnLine Bom 1841; <https://indiankanoon.org/doc/160266477/>

Artificial intelligence/machine learning technology-based platforms are not authorized for telemedicine consultations or medication prescribing, although they may help the certified medical practitioner in arriving at a sound conclusion while determining the treatment for the patient concerned.

If a digital platform is proven to be in breach of the Guidelines, it might be banned, and no licenced medical practitioner could use it to provide telemedicine. RMPs who continue to use a banned telemedicine platforms and provide services through the same however face no special penalties. The final prescription or recommendation must always come from a Registered Medical Practitioner. Telemedicine platforms must also have enough processes in place to answer any queries that patient may have

Limitations

- 1) The Telemedicine Practice Guidelines only apply to healthcare practitioners who are licenced under the MCI Act; i.e they only apply to Allopathy practicing doctors registered with a particular State council. They do not apply to dentists or other telemedicine providers.
- 2) The Telemedicine Practice Guidelines don't give enough advice on how to get patients' informed consent or how to use their personal data.
- 3) When patients consult with individual RMPs using informal messaging applications, it is the RMP's obligation to secure patient data in accordance with India's data protection regulations. However, due to the fact that India's data protection laws cannot be enforced on individuals, patient data supplied to individual RMPs is practically unprotected.
- 4) List B drugs can only be prescribed via telemedicine if they were previously prescribed in person by the same RMP. There is no provision, however, for a situation in which the prescription was previously administered during an in-person session with an RMP other than the one contacted through a telemedicine platform.
- 5) Consultation for minors by RMP requires the presence of an adult at all times. While this allows for well required adult supervision, on the other side, this could provide problems for children who want to discuss sensitive topics without consulting their parents or guardians, such as mental health or reproductive health consultations.

Policy Suggestions

All aspects of telemedicine practise need to be regulated by the government. To provide further security, special safeguards in the TPG should ensure a basic degree of data protection for health data submitted during a teleconsultation. This would also ensure that any unsolicited health information provided by the patient is suitably safeguarded. It's also important to simplify the definitions of follow-up consultations. In addition to this, the six-month gap between in-person sessions should be eliminated. These initiatives will assist India in streamlining its Telemedicine practise, which has the potential to improve healthcare access in the country.

Conclusion

Telemedicine may not be the answer to all problems, but it can be a significant step in transforming India's healthcare system. The government must take significant steps to make it simpler for the people to adapt to this system and for telemedicine to realize its full potential.