

TELEMEDICINE: A GLOBAL APPROACH TO TRENDS AND PRACTICES

Authors: Sameer Sah, Sayani Bhattacharyya, Sumantra Bose and Tashi Gyanee, Khaitan & Co

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LAWS AND REGULATIONS ON TELEMEDICINE

1. Is telemedicine allowed in your country? If so, how is it defined?

Telemedicine is permitted in India, and against the backdrop of the recent Covid-19 pandemic, telemedicine is now heavily supported by Government of India initiatives. The Telemedicine Practice Guidelines published on 25 March 2020 (the 'TPG') defines 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'.

2. Please provide a high-level overview of the legal framework regarding telemedicine in your country.

While India does not have any specific act governing telemedicine in India, the TPG has been introduced as a part of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (*as adopted by the National Medical Commission which has superseded the Medical Council of India*), and consultations through telemedicine by registered medical practitioners (RMPs) are permissible in accordance with provisions of the TPG. The TPG is designed to serve as an aid and tool to enable RMPs to effectively implement telemedicine in India. Please note that the TPG is not applicable to the use of digital technology to conduct surgical or invasive procedures remotely.

Telemedicine is further subject to compliance with Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (the 'Ethics Regulations') and the overall regulatory framework governing medical profession in India, including but not limited to the Drugs and Cosmetics Act, 1940 and rules made thereunder; Pharmacy Practice Regulations, 2015; National Medical Commission Act, 2019 (the 'NMC Act'); and the regulatory framework governing data protection, inter alia, including the Information Technology Act, 2000 (the 'IT Act'); Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 (the 'Data Protection Rules') and Information Technology (Intermediaries Guidelines) Rules, 2011 (the 'Intermediary Guidelines'); Other Service Providers Regulations under the New Telecom Policy 1999 (the 'OSP Regulations'); and government policies regulating health-related data in India.

3. Briefly identify the key licensing bodies for telemedicine and outline their responsibilities.

The key licensing bodies for telemedicine are the same for RMPs providing telemedicine as other physicians conducting physical consultations (*this, however, does not include dentists or homeopaths, or practitioners of traditional medicine*). In India, an RMP is defined as a person who is enrolled in a state medical register or the Indian medical register under the National Medical Commission Act, 2019, and all RMPs are eligible to practise telemedicine subject to the provisions of the TPG. RMPs in India are regulated at the central level by the National Medical Commission (NMC).

Please note that homeopaths are required to be registered under the Homeopathy Central Council At, 1973, and are regulated by the Central Council of Homeopathy, which has released

a separate set of telemedicine practice guidelines applicable to homeopathic practitioners. Practitioners of traditional medicine are also permitted to provide telemedicine under a separate set of telemedicine guidelines published by the Central Council of Indian Medicine, if such practitioners are registered with the concerned state registers of practitioners of traditional medicine.

Service providers who render 'Application Services', which includes telemedicine services, using telecom resources provided by telecom service providers may be required to be registered as an 'Other Service Provider' (OSP) with the Department of Telecommunications. Generally, OSP registration requires the registration holder to comply with certain conditions as part of the licence. Service providers that hold an OSP licence are companies or limited liability partnerships, or other firms or organisations established in India, and do not include individuals.

The National Health Authority, Ministry of Health and Family Welfare (the 'NHA') has launched a free telemedicine service in India called eSanjeevani, under Ayushman Bharat Digital Mission, and healthcare professionals (HCPs) seeking to, inter alia, provide telemedicine in India may get registered in the HCPs registry maintained by the NHA.

4. Was telemedicine authorised during the Covid-19 pandemic?

Yes, in fact, the release of the TPG was expedited in light of the Covid-19 pandemic. The guidelines primarily provide guidance on the process of consulting remotely rather than the regulation of the consulting platform, but most importantly, they recognise tele-consultations.

5. Is there any possibility of the regulatory landscape being changed in the post-pandemic scenario or has there already been a change in regulation in the post-pandemic scenario?

We do not anticipate that these guidelines will be revoked. However, in the post-pandemic scenario, the NMC published draft National Medical Commission Registered Medical Practitioner (Professional Conduct) Regulations, 2022, along with a draft revised TPG. The draft TPG, 2022 has some new requirements; for example, it is proposed that telemedicine service providers should establish protocols for referrals to emergency services. Further, RMPs may not participate in telemedicine platforms that provide ratings by patients or others, including reviews, advertisements and promotions of RMPs by any means. Additionally, there is a proposal for the entire onus of ensuring that RMPs providing telemedicine on the service providers' platform are duly qualified and registered with all particulars authenticated to be shifted onto the owners and administrators of the technology platform.

6. What types of teleservices are allowed (eg, second opinion, teleconsultation, telediagnosis and telesurgery)?

The TPG expressly allows for: (1) teleconsultation, including the first consultation and follow-up consultations with same RMP in non-emergency situations; (2) teleconsultation in emergency situations in the absence of alternative care; (3) telediagnosis; (4) telemonitoring and screening where physical interaction is not required; (5) teleconsultation between RMPs and nurses, allied health professionals, midlevel health practitioners or any other designated health worker; and (6) teleconsultation between RMPs, including with respect to teleradiology, teleophthalmology and telepathology.

Note that TPG does not permit the usage of telemedicine to conduct surgical and invasive procedures remotely. Further, certain drugs, such as narcotic and psychotropic drugs, cannot be prescribed over teleconsultations. However, some anti-anxiety and sedating drugs, such as clonazepam, phenobarbitone and clobazam, are permitted to be prescribed in the first consultation, as well as follow-up teleconsultations.

7. Who can use telemedicine services? Please indicate whether only doctor-doctor or also patient-doctor remote medical services are allowed.

Anyone who has consented to telemedicine consultation can enjoy telemedicine services

(patients opting for telemedicine are deemed to have provided implied consent), as long as the responsible physician does not refuse telemedicine and indicates, otherwise, the need for in-person medical consultation. All doctor-doctor, doctor-healthcare provider and patient-doctor telemedicine services are allowed, provided that any health worker taking telemedicine services on behalf of a patient obtains the explicit consent of the patient concerned.

8. Please outline the funding model for telemedicine. Is it available in your jurisdiction's public health system? Is telemedicine under mandatory insurance coverage? Please indicate what legislation applies.

In India, other than private platforms providing telemedicine services to doctors and patients, the Government of India, through the eSanjeevani platform, which was established on a doctor-doctor level in 2019 and patient-doctor consultation level in April 2020, has facilitated telemedicine access in most Indian states and now forms part of the public health system. As per guidelines issued by the Insurance Regulatory and Development Authority of India (IRDAI), insurance companies are now advised to allow telemedicine wherever consultation (ie, outpatient department consultation) with RMPs is allowed under the terms and conditions of the insurance policy document.

9. Please indicate whether any insurance requirements are applicable to telemedicine service providers.

Note that this varies from policy to policy and insurer to insurer, and patients in India tend to procure private medical/healthcare insurance. There are currently no insurance requirements applicable to telemedicine service providers.

REQUIREMENTS APPLICABLE TO HEALTHCARE PROFESSIONALS AND INSTITUTIONS

10. Who can practise telemedicine in your country? Please indicate whether other healthcare professionals are authorised to provide remote health services under the applicable rules (eg, nurses, psychologists, nutritionists and alternative health therapy providers).

Practitioners of each system of medicine are regulated or supervised by their specific professional council that defines the standards of professional practice, and supervises professional ethics and good practice in the services.

While the Ethics Regulations permit RMPs to provide telemedicine services, separate telepsychiatry guidelines were published in April 2020 to guide telepsychiatry services. Similarly, separate telemedicine guidelines also exist for homeopaths and traditional medicine practitioners.

11. Are there any specific education requirements or training that healthcare professionals need to meet or attend to provide telemedicine services?

Multiple regulations regulate the licensing and registration of HCPs in India, whereby HCPs, including RMPs, dentists, physiotherapists, psychologists and pharmacists, are all required to be duly qualified, possess valid registration and/licences, and ensure compliance with several requirements to practise their profession. Other HCPs, such as nurses, and other allied professionals and HCPs are also required to be registered under the applicable state or central register, as the case may be.

Note that telesurgery and so on are presently not covered under the TPG or the draft TPG, 2022.

Under the TPG, online programmes may be conducted for RMPs to become familiar with the TPG, and the process and limitations of telemedicine practice. All RMPs intending to provide online consultation are required to complete a mandatory online course within three years of the notification of the TPG.

12. Is there any registration requirement applicable to physicians that provide

telemedicine services?
RMPs and other HCPs may be required to be registered with the NHA for the provision of nationwide telemedicine services as facilitated by the Government of India. Other than registration with the NHA, regular registrations and licences for practising the profession continue to apply.
13. Please indicate whether special licenses or authorisations are mandatory for institutional healthcare providers engaged in telemedicine services.
Institutional healthcare providers may be required to be registered with the NHA under the Ayushman Bharat Digital Mission for the provision of telemedicine and associated tele-healthcare services.
REQUIREMENTS APPLICABLE TO TELEMEDICINE SERVICES
14. Are there specific requirements applicable to the telemedicine platform?
<p>Companies, limited liability partnerships (LLPs), firms or other legal entities that provide telemedicine services in India are required to be registered and/or established in India, as the case may be. Such entities may be required to be registered with the NHA as well.</p> <p>Further service providers who render application services, including those that provide telemedicine services using telecom resources provided by telecom service providers, are required to be registered as an OSP with the Department of Telecommunications.</p> <p>While under the extant TPG, the onus for maintaining a digital trail of consultation for a prescribed period is on the concerned RMP, the draft TPG, 2022 proposed that the entire onus for collecting, storing and retaining health and consultation records, including the onus for following data privacy rules in India, should be imposed on the telemedicine platform. Currently, technology platforms are required to ensure that the RMPs using the platform are duly registered with national medical councils or the respective state medical council and comply with relevant provisions, and report any RMP non-compliance immediately to the regulatory authorities. Note that while artificial intelligence (AI), the Internet of Things, advanced data science-based decision support systems and so on could assist and support an RMP in patient evaluation, such a platform cannot counsel or prescribe any medicinal product to any patient – only an RMP is authorised to do so. Note that under the TPG, technology platforms are required to ensure that there is a proper mechanism in place to address any queries or grievances that the end-customer may have.</p>
15. Are there any requirements regarding electronic equipment and internet speed for telemedicine services?
There are no legal requirements regarding electronic equipment and internet speed for telemedicine services. The TPG specifically excludes any specification for hardware or software, infrastructure building and maintenance, data management systems involved, and standards and interoperability.
16. Does legislation provide for specific rules concerning patients' medical records?
<p>As per the TPG, an RMP is required to maintain the below records/documents for the period as prescribed from time to time:</p> <ul style="list-style-type: none">• log or record of telemedicine interaction (eg, phone logs, email records, chat/text record and video interaction logs);• patient records, reports, documents, images, diagnostics, data and so on (digital or non-digital) utilised in the telemedicine consultation; and

- in the case in which a prescription is shared with the patient, the prescription records as required for in-person consultations.

As health records are classified as sensitive personal data or information, any telemedicine platform collecting and/or storing such data is required to comply with Indian data privacy laws under the IT Act, Data Protection Rules, Intermediary Guidelines and so on. Further, any RMP collecting patient data is subject to professional secrecy obligations under regulations issued by the NMC.

17. Are there geographic location requirements applicable to the provision of telemedicine services?

A telemedicine platform may only be provided by legal entities registered and/or established in India. There is no prohibition of inter-state consultations between patients and doctors located in different states of India.

18. Does the healthcare professional need to obtain the patient's consent to engage in telehealth?

As per the extant TPG, patients who access telemedicine platforms are deemed to have given implied consent to engage in telehealth. Explicit patient consent is needed in the event that a health worker, RMP or caregiver initiates a telemedicine consultation on behalf of the concerned patient. Such explicit consent can be recorded in any form – through email, text, audio/video message and so on. The RMP being engaged in such a teleconsultation is required to record this explicit consent in his/her patient records.

In the case in which an RMP transmits a prescription directly to a pharmacy, the RMP is required to ensure the explicit consent of the patient that entitles him/her to get the medicine dispensed from any pharmacy of his/her choice. Please note that any transfer of health data, being sensitive personal data or information, requires the consent of the patient and strict compliance with the IT Act and Data Protection Rules.

Please further note that the data privacy legal regime in India, along with health data management, is undergoing an overhaul and our answers with respect to data privacy concerns may differ once the new legal framework has been brought into effect.

19. Is there any other important requirement that should be highlighted?

In the event that the RMP has prescribed medicine, RMP is required to issue a prescription in accordance with the provisions of the Ethics Regulations and in compliance with the provisions of the Drugs and Cosmetics Act, 1940. As highlighted in our response to item 6, please note that certain drugs (drugs under Schedule X under the Drugs and Cosmetics Act, 1940 and drugs specified under the Narcotic Drugs and Psychotropic Substances Act, 1985) are not permitted to be prescribed in teleconsultations, unless otherwise notified. To issue a prescription, the RMP is required to explicitly ask the age of the patient, and if there is any doubt, seek proof of age. Where the patient is a minor, after the age is confirmed, teleconsultation may be allowed only if the minor is in the consultation with an adult whose identity needs to be ascertained.

RMPs are required to provide a photo, scan or digital copy of the signed prescription or e-prescription to the patient via messaging, email or any other platform.

DATA PRIVACY ASPECTS

20. Are there data privacy issues that should be considered for the exploitation of such a market? If your answer is yes, please provide a short description.

Yes, there are data privacy issues that should be considered for the exploitation of the telemedicine market. Patients' medical records, being sensitive personal data or information, are required to be collected and processed in compliance with the IT Act, Data Protection Rules, and

Intermediary Guidelines and privacy laws or any applicable rules notified from time to time, and regarding the handling and transfer of such personal information regarding the patient.

Further, RMPs are required to fully abide by the Ethics Regulations for protecting patient confidentiality. However, RMPs are not held responsible for breach of confidentiality if there is reasonable evidence to believe that the patient's privacy and confidentiality were compromised by a technology breach or by a person other than the RMP.

As set out in our response to item 16 above, the TPG requires RMPs to maintain certain records/documents for a prescribed period, and all such patient data is required to comply with extant data privacy laws in India. Further, as per the Ethics Regulations, every physician is required to maintain medical records pertaining to his/her indoor patients for a period of three years from the date of commencement of the treatment in a standard prescribed pro forma.

21. Does the applicable regulation provide for criteria and requirements for security systems to protect the patient's information?

Under the IT Act, bodies corporate that possess, deal or handle any sensitive personal data or information are required to maintain reasonable security practices and procedures. As per the Data Protection Rules, a body corporate is considered to have complied with reasonable security practices and procedures if it has implemented such security standards, and has information security programmes and policies that contain managerial, technical, operational and physical security control measures that are commensurate with the information assets being protected with the nature of business. The Data Protection Rules further recognise International Standard IS/ISO/IEC 27001 on 'Information Technology – Security Techniques - Information Security Management System – Requirements' as being such an acceptable standard.

The directions published by the Indian Computer Emergency Response Team (the 'CERT-In Directions') also provide for several compliances relating to information security practices, procedures, and the prevention, response and reporting of cyber incidents as are applicable to body corporates, that is, companies (including firms, sole proprietorships or other associations of individuals) engaged in commercial or professional activities.

While India does have guidelines pertaining to electronic health records (EHRs), note that they have not yet received regulatory sanction, and so compliance with the EHR guidelines remains a voluntary good hygiene measure instead of a mandatory obligation.

22. Does the applicable regulation provide for requirements for the transfer of information abroad?

Yes, the Data Protection Rules (which operate on a sector-neutral basis and govern the processing of sensitive personal data and information) state that an entity may transfer sensitive personal data and information to any other entity, in India or overseas, that ensures the *same level of data protection* that is adhered to by the transferring entity, as is prescribed under the Data Protection Rules. The transfer may be allowed only if: (1) it is necessary for the performance of a lawful contract between the transferring entity and the information provider; or (2) where such an information provider has consented to the data transfer.

23. Is there any registration of databases requirement that companies must observe? Are there requirements regarding the recording of data in the patient's medical records?

No, there are no such registration or record-maintenance requirements prescribed under the IT Act and the rules framed thereunder. Please refer to our response to item 16 for the information required to be recorded by the concerned RMPs in patients' medical records.

LIABILITIES

24. Please provide a high-level overview of the liability of healthcare professionals and

institutions involved in telemedicine practices.

The consequences of medical negligence-related liability in India can broadly be put into three categories: (1) criminal liability; (2) monetary liability; and (3) disciplinary action. Criminal liability can be fastened pursuant to the provisions of the Indian Penal Code, 1860 (the 'IPC'), which are general in nature and do not provide specifically for 'medical negligence', but however, form the grounds of criminal prosecution for death by rash or negligent act, grievous hurt, causing hurt and so on by HCPs. Note that for a successful criminal prosecution for medical negligence, it is required that '*mens rea*' is proven. HCPs may be liable to pay monetary compensation as a civil liability before an appropriate civil court or consumer forums (under the Consumer Protection Act, 2019).

In addition to the above, HCPs may also be subjected to disciplinary action and face penalties thereunder for professional misconduct causing harm to patients under the scope and ambit of the Ethics Regulations. The NMC and appropriate state medical councils are empowered to take disciplinary action, whereby the name of the practitioner could be removed forever or be suspended. In the case of damages to the patient as a result of the service rendered by the professional, the hospital or institution is liable, unless the institution proves that: (1) there was no damage caused to the patient; and (2) the damage resulted from the acts of the patient himself/herself or a third party. The aforementioned liabilities are applicable to telemedicine as well.

Further, in the event of the violation of Indian data privacy laws, under section 43A of the IT Act, an entity that is negligent in implementing and maintaining reasonable security practices and procedures for the protection of sensitive personal data or information, and thereby causes wrongful loss/wrongful gain to any person, may be required to pay damages by way of compensation to the person so affected. The quantum of compensation is uncapped and is decided on a case-by-case basis.

TELEMEDICINE NUMBERS AND TRENDS

25. Is there any public disclosed information concerning the use and acceptance of telemedicine in your country?

In April 2020, the Government of India launched the eSanjeevani telemedicine service that operates at two levels: doctor-to-doctor telemedicine platform and doctor-to-patient platform. As per the government news bulletin dated 25 March 2022, the eSanjeevani platform had recorded over 30,000,000 teleconsultations. As per various projections conducted by private bodies, the Indian telemedicine market is expected to exhibit an average compound annual growth rate (CAGR) exceeding 20 per cent in the period between 2022 and 2025. With the incremental digitisation of remote and rural areas of India, the telemedicine market is expected to reach exponential heights in the coming decade.

26. What are the perspectives and trends in relation to the matter for the next few years? Please outline any unresolved issues, proposed changes or trends for the telemedicine sector and briefly indicate how these may foreseeably affect medical practice in the near future.

The most important trends expected for the market are:

1. telemedicine market growth and segmentation into various specialties;
2. boost in ancillary telemedicine industries, such as wearables manufacturing for checking various health reports;
3. incremental focus on stringent data privacy laws;
4. anticipated increase in robotic surgery, followed by the introduction of corresponding regulations;
5. growth in the use of home monitoring systems, smartwatches and smartphone applications;

6. increased usage of EHRs and electronic medical record databases; and
7. amplification of digitisation in India.