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Healthcare Update

Telemedicine in India

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Legal Position concerning Telemedicine in India

The World Health Organization (“WHO”) defines Telemedicine as “The delivery of healthcare services, where distance is a critical factor, by all healthcare 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 healthcare providers, all in the interests of advancing the health of individuals and their communities”.

Despite the concept being recognized and defined by WHO and its spreading influence over the past decade, there is no legislation which singularly deals with the practice of Telemedicine in India.

In the absence of a specific law, as the practice of Telemedicine is fundamentally an intricate combination of ‘the practice of medicine’ with ‘information technology’, undoubtedly all the existing laws relating to both ‘medicine’ and ‘information technology’ in India would apply to Telemedicine.

Hence, the practice of Telemedicine in India is governed by various statutes that generally relate to the practice of ‘medicine’ in India such as the Medical Council of India Act, 1956 (“MCI Act”) and the rules and regulations issued there under and state specific legislations where the business is proposed to be established. In terms of the MCI Act, once a doctor/medical practitioner is qualified and registered in any one of the state medical registers maintained by the respective states, a copy of his/her registration certificate is forwarded to the Medical Council of India for enrollment of his/her name in the Indian medical register (national database). In terms of Section 27 of the MCI Act, any person whose name is enrolled in the Indian medical register can practice as a medical practitioner in any state of India according to his qualifications. Hence, inter-state practice of Telemedicine by medical practitioners is permissible.

Recommended by:



For all medical treatments through telemedicine or web-interface format, it is important to ensure that the prescriptions issued by the medical practitioner satisfy the requirements of being in writing and signed by a registered medical practitioner, in accordance with the Drugs and Cosmetic Rules 1945, without which, the prescription will be invalid in the eyes of the law.

Telemedicine would also be governed by the Information Technology Act, 2000 which provides for standards in relation to information technology in general although it does not relate to the provision of healthcare services by using information technology. Issues related to security, privacy and confidentiality of patient data and potential misuse and even abuse of electronic records in the form of unauthorised interception and/or disclosure would need to be considered.

In the absence of any central or overarching legislations providing for registration or licenses for practicing Telemedicine in India, state specific laws governing the practice of 'medicine' generally have to be considered.

Recommended Guidelines & Standards for Practice of Telemedicine in India

The Department of Information Technology, Ministry of Communications and Information Technology issued Recommended Guidelines & Standards for Practice of Telemedicine in India ("**Guidelines**") in May, 2003. As the name suggests, these Guidelines are not binding, although it is advisable to follow them as various issues arising from Telemedicine have yet not been tested by Indian Courts.

The Guidelines delineate the necessary information in terms of introduction to Telemedicine, including, definitions and concepts, standards required for hardware, software and clinical devices, including the security aspects and finally the Telemedicine process guidelines.

The Guidelines recommend that each healthcare provider should have a unique provider identifier which will flow to all its programs and telemedicine consultation centres ("**TCC**"). Each of the telemedicine speciality centres ("**TSC**") and TCCs are also recommended to have a separate unique and universal identifier code. It is further recommended that each patient also be identified by a unique and universal patient identifier so that one central patient information record can be assimilated, comprehensive medical databases can be built, or if the patient wants, he/she can move across multiple providers without losing data.

The Guidelines also spell out the hardware and software (including detailed configuration and specifications) which is recommended for the setting up of the TCC and TSCs. In the absence of a legislation governing Telemedicine, it is suggested that the machinery and equipment of the vendor complies with the specifications given in the Guidelines so as to dilute potential liability issues at a later stage.

The Guidelines provide adequate risk mitigation at various stages in the process of Telemedicine and thereby must be closely consulted while setting up Telemedicine organizations.

Some of the popular Telemedicine business models prevalent in India include captive and incentivized multi-tier structures. While the captive model (in which the TSC and the TCC are owned and controlled by the operating entity) opens up a myriad of liability issues for the operating entity vis-à-vis the employees, local regulations applicable to operating diagnostic centres, TSC and TCC, etc. and involves a substantial investment in equipment and networking infrastructure, the incentivized model (a franchise based outsourced model) is usually aimed at minimizing the liability exposure on the operating entity since most of the inter-tier work force is outsourced based on an incentive structure.

For entities not otherwise engaged or established in the medical services sector, an incentivized multi-tier structure is the preferred option to minimize the liability exposure on the operating entity. However, a captive structure offers greater functional autonomy, though it requires larger seed investments as well.

Feedback

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