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Regulatory Compliance of Telemedicine Applications in India: An Analytical Study

Ms. Shraddha Nigade,

Research Scholar,

M.C.E. Society's A.K.K.

New Law Academy Ph.D (Law) Research Centre,

Savitribai Phule Pune University, Pune

Abstract-

Healthcare delivery in India has changed substantially through the blistering growth in the telemedicine applications, which have increased access, affordability, and efficiency. Various regulatory responses to regulate virtual medical consultations were boosted by the COVID-19 pandemic which enhanced the use of digital health platforms. In this paper, the author discusses the regulatory compliance of the major telemedicine platforms in India in terms of the Telemedicine Practice Guidelines, 2020, which were issued by the National Medical Commission and the Information Technology Act, the Digital Personal Data Protection Act, the Drugs and Cosmetics Act, and the Consumer Protection Act. The paper critically assesses the compliance of the major telemedicine applications with the requirements of the law concerning practitioner eligibility, informed consent, data protection and cybersecurity protection, tele-prescription standards, and platform liability. It also evaluates regulatory uncertainties relating to whether or not telemedicine platforms should be classified as intermediaries, healthcare service providers, or digital health facilitators and whether or not this has any implication on accountability. Through identifying areas of noncompliance and structural overlaps in the regulation of healthcare and digital data, this paper examines how the Indian telemedicine regulatory framework is fragmented. The study contends that, although the current framework offers the basic protection, enhanced statutory integration, more robust enforcement mechanisms, and coordinated digital health governments are required to provide patient protection without frustrating innovation. The paper ends with findings on how to improve regulatory coherence and accountability in the emerging sector of telehealth in India.

Key Words- Telemedicine, Digital Health, Regulatory Compliance, Data Protection, Platform Liability



Introduction –

World Health Organisation uses e-Health as Information technologies Health. In 2018 the World Health Assembly recognized the opportunities of digital technologies in making a significant contribution to the population health with delegates coming to an agreement on a resolution on digital health. The resolution encourages the member states to develop and use digital technologies in health more as a way of promoting Universal Health Coverage and sustainable development goals. In India, this term is used interchangeably with Telemedicine. Hence, it can be stated that Digital health refers to the application of Information technology tools and services to make different healthcare facilities available to the needy people. We usually encounter other applications/ websites in which medical practitioners can offer consultancy to patients without physically meeting them. When visiting such apps/websites, we post all kinds of information, including ours and our health, which is subsequently accessed by the medical practitioners and is used to diagnose. The issue relating to such practice is the security of the data/ information submitted by user. The above practice is not the only practice prevailing in the provision of telemedicine but encompasses various other practices that include e-pharmacies, robot assisted surgery, self monitoring healthcare equipment, electronic health records and many more. Among all these practices abovementioned, much of the data / information that is personal or sensitive in nature may be acquired and utilized without permission. Therefore, digital health services⁴ are obligatory to be governed in India.

According to Chief Scientist of WHO, the use of digital technologies provides new opportunities to enhance the health of people. However, difficulties in the effect of certain interventions are also noted in the evidence that chief scientist points out. The difficulties include with regards to data protection. Undoubtedly, the intrusion of technology in the healthcare sector can perform miracles and will assist in the universal coverage of health, but simultaneously, people need to be convinced that their information is in safe hands with the individuals offering digital health services. Since Telemedicine is mainly a complex combination of the practice of medicine as well as information and communication technology, in absence of a specific law, all the existing laws in India addressing both to medicine and to information technology would definitely apply to Telemedicine. The chapter talks about the different regulatory framework in India on Telemedicine.

Telemedicine -

Any software that is utilized in some of the identified purposes is classified as a medical device in the Indian law. In 2020, a change was made to purchase software as a medical device under the Drugs and Cosmetics Act, 1940 (the main law concerning medical devices) (D&C Act).

Software can be considered as a medical device provided it is utilized with the following purposes: Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder. Diagnosis, supervision, care, relief or support of any injury or disability, Research,



replacement or other alteration, or support of anatomy or a physiological process, Maintenance or support of life, Disinfection of medical equipment. Control of conception. Medical devices (including software) under the Medical Devices Rules, 2017 (MD Rules) fall into 4 categories of risk-based classifications (Class A - low risk, Class D - high risk). This also involves software in the form of digital health applications which are utilized in any of the above purposes., As an illustration, photoplethysmography analysis soft-ware, as a home analysis of data obtained through fitness machines like Fitbit devices, qualifies as a Class B (low- moderate risk) medical apparatus.,

Main Regulations concerning Telemedicine regulation-

Consumer Protection Act, 2019: Digital health apps that are in the form of software are regarded as a product under the CPA 2019, unless the software is acquired to sell it, or to sell it commercially. CPA 2019 is applicable to manufacturers and service providers and sellers of digital health software, and does not exclude the transparency, fair trade and the redress to consumers.

Contract Law: The Indian Contract Act of 1872 also provides a liability in case the developer or service provider violates any end user agreement or terms of service.

In CPA 2019 product liability actions can be subject to exceptions of some of them. There are exemptions to liability of a manufacturer, service provider or seller of a product, such as: (i) a seller of a product is not liable in circumstances where the product was misused, altered, or modified by the consumer; and (ii) a manufacturer is not liable due to a deficiency in the delivery of warnings and instructions in circumstances where the consumer, in the course of using the product, was under the influence of alcohol. Liability may also be capped using disclaimers or limitation of liability provisions in user agreements under contract law, although these should be reasonable and enforceable.

Other Regime -

Additional legal regimes relative to data protection that concern digital health software (gathering information that relates to medical records) do exist in India-

The Information Technology Act 2000 in India-

The Information Technology (Reasonable security practices and procedures and sensitive personal data) Rules, 2011 (SPDI Rules) are the main regulatory instruments that apply to the collection, receipt, processing, storage, transfer, dealing of personal information and sensitive personal data or information by various entities/businesses. Personal information This is any information that is related to a person, and which can identify such a person. The SPDI, being a sub- set of the Personal Information, inter alia, comprises medical record and history among other such information; as well as information relating to the physical, psychological and medical health of an individual. Infringement/unauthorized disclosure of such information



may lead to damages claims, in addition to penalties to be imposed upon the violation under the IT Act.

Besides the above data protection framework, the legal framework applicable in cyber security also applies to the digital health apps/software. In this respect, the IT Act as it is read together with the: (i) Information Technology (The Indian Computer Emergency Response Team and Manner of Performing Functions and Duties) Rules, 2013, and (ii) Directions relating to information security practices, procedure, prevention, response and reporting of cyber incidents dated April 28, 2022 specify the procedure that should be adhered to by different parties in the case of a cyber security incident. This involves reporting provisions that shall be followed in case of suspicion / having knowledge of such incident. Any violation can lead to serving of other people in jail and fines according to the IT Act. The Supreme Court acknowledges the right to privacy of an individual as a right to life under Article 21 of the Constitution of India, 1950.

DPDP Act would be used in the processing of personal data, i.e. any data about an individual identifiable by or in relation to such data in a digital form. In contrast to the SPDI Rules, the DPDP Act does not make a distinction between the various types of personal data and covers the health related data as well. It is worth mentioning, though, that the duty of adherence to the requirements in the DPDP Act will be imposed on the data fiduciaries only (excluding the data processors) to the extent that it is possible. Any violation can lead to penalty as prescribed in DPDP Act.

The management of the electronically available health records is regulated by the Electronic Health Record Standards, 2016, or EHRS, which is published by the Ministry of Health and Family Welfare. The EHRS include detailed instructions touching on the data access measures, the confidentiality requirements, and security measures of the health information stored in an electronic form. The EHRS restates the applicability of the IT Act (with amendments) and the SPDI Rules as pertaining to collection, processing and maintenance of confidentiality of health information. Some other standards such as the guidelines of Good Clinical Laboratory Practices provided by the Indian council of Medical Research (published under the New Drugs and Clinical Trials Rules, 2019), which requires some data protection measures on health related data might apply in some situations when such sets of data are handled.

IT Act, SPDI Rules and Cert-In Framework-

IT Act and Cert-In Framework: The applicability of the IT Act (and the underlying Cert-In Framework) includes: (i) all persons (including natural and juristic persons) in India, irrespective of their nationality/residency; and (ii) any offence or contravention committed outside India, but where the act or conduct that constitutes the offence or contravention is conducted in India involving a computer, computer system or computer network ("Computer"). In this regard, the IT Act shall be applicable where (a) the data is being processed by users



and/or entities; (b) the processing of the data is being done in India. With this said, it has to be pointed out that in some rare cases, where all of the parties are not in India, but the Computer is in India the IT Act may be applicable and this will have to be looked at on a case-by-case basis.

SPD/ Rules: The compliance provisions of the SPDI Rules would only apply to body corporates or individuals within India. In the case where the body corporate and the individuals are not in India, then the SPDI Rules may not be relevant. Nevertheless, even where there has been an unauthorised access to a Computer in India, then the body corporate can still be liable under the IT Act.

DPDP Act-

The DPDP Act is applicable: (i) when processing any personal data in the territory of India is done; and (ii) when any digital personal data is processed outside the territory of India, but the processing occurs in relation to the provision of goods/services to data principals in India. To this extent, the DPDP Act would apply in a case where the processing of sets of personal data (data fiduciary) is being conducted in India, or the processing activity undertaken by the entity is directed towards the provision of services in India. The principal regulatory authority over physicians in India is the National Medical Commission also known as the National Medical Commission Act 2019 referred to as the NMC. In 2020, the NMC supersedes the Medical Council of India. Besides the NMC, individual states also have their State medical councils. The NMC Act is in control of the State Medical Councils and stipulates registration of medical practitioners and a register of medical practitioners. The conduct of such practitioners is also regulated by the State Medical Council through taking complaints of the citizens and has the authority to reprimand or suspend such practitioners and take the name of the name off the register. Physicians are also mandated to follow regulations written by the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 which stipulates the roles and behaviour that are expected of the physicians.

The legislation and rules governing telemedicine in physician-

Besides the above-mentioned laws, another regulation regulating the work of physicians operating telemedicine in India is the Telemedicine Practice Guidelines, 2020 issued by the Ministry of Health and Family Welfare. These regulations are a legal criterion under which registered medical practitioners (RMPs) refer to their patients remotely, through the different communication platforms. According to the Telemedicine Guidelines, it is up to the discretion of the physician whether or not telemedicine was applicable to treat a patient. When a doctor concludes that a patient is treatable by use of telemedicine, the Telemedicine Guidelines govern the use of telemedicine.

The conditions stipulated by the Telemedicine Guidelines are:

The doctors will be required to be registered by the NMC or a state medical council. The



teleconsultations ought to be held on the necessary technology platforms that ensure privacy and confidentiality of patients. Doctors should seek the consent of the patient - the consent is presumed in case the patient initiates the consultation, but explicit consent is necessary in some situations. Doctors are required to make professional decisions on whether a teleconsultation should be conducted or a visit done. Teleconsultation prescription has to be according to the Telemedicine Guidelines. Some of the medicines with potential to abuse and may harm the patient or the whole society in case of wrong use cannot be prescribed remotely under teleconsultations. The teleconsultations should be properly documented and recorded.

Based on the Telemedicine Guidelines, physicians are required to seek patient consent prior to giving teleconsultation. To this effect, consent may be:

Implied consent: In case the patient takes the initiative of a consultation. Implied consent is necessary under certain conditions, like sharing patient information with another healthcare organization or prescribing medication. The physicians must educate patients about: The shortcomings of telemedicine as compared to face-to-face consultation such as the possibility of risk of lack of physical examination. This is because teleconsultation limits and types, including privacy and data security protocols. The right of the patient to request a face-to-face consultation at any moment. Though there is no standardised form of the disclaimer, the physicians need to convey these issues clearly during the consent procedure and the interaction needs to be well-documented.

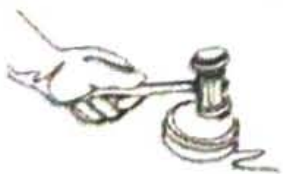
Questions-

Q1. Is there a risk of liability increase due to the use of telemedicine (e.g., when a physician is requested to certify that someone is fit to work in a specific job and does it remotely compared to the face-to-face consultation)?

The quality of care required of the physicians will not change regardless of the mode of consultation, whether it is through telemedicine or in-person consultation. However, The use of telemedicine can create a risk in liability when the doctor who is not present is not using sufficient clinical judgment in deciding when remote consultation should be used or when they do not consider physical examination necessary in complicated Cases. In activities like certifying suitability to work or a medical certification, virtual assessments could be criticized as lacking rigor and this could increase the liability risk. Doctors should be very careful and possibly suggest physical examination where necessary. Finally, it is a matter of liability in relation to whether the physician acted within the accepted medical standards and Telemedicine Guidelines or not.

Q2. Is there any limitation on the nature of medicine that is prescribable under telemedicine?

Yes, the Telemedicine Guidelines establish strict limitations on the kind of medicine prescribable using telemedicine. It has classified medicines under the Telemedicine Guidelines as medicines that can be prescribed using telemedicine and those that are not



Telemedicine Practice Guidelines of 2020 has already begun this process and, still needs governmental support, including subsidies on the privately side.

It will include the telemedicine programs and investments in digital infrastructure. In addition, telemedicine prescriptions, despite being a significant development, are not verified, lack legal provisions, and data privacy, which should be included. In this direction, there are different technological advances made, which contribute to the risk of losing oneself in a different dimension. Technology Telemedicine will also be integrated into an accessible, patient-centered healthcare delivery base that bridges the disparities in the different healthcare ecosystem. The revolution of health care system within India through telemedicine is possible but it should overcome the challenges by enhancing the policies, investing in infrastructure and educating the people on how to implement the health care system through telemedicine in a fair and sustainable way. With adequate support and infrastructures, telemedicine will be an inseparable component of Indian health system and it will be able to provide quality care to patients throughout the country.

Several technologies will transform the healthcare in the future. The contribution of AI will also play an important part because AI-driven diagnostics and predictive analytics will enable to diagnose diseases at an early stage, develop a tailor-made treatment regimen, and enjoy improved patient outcomes. The Internet of Things will become a tremendous difference, too: wearables and sensors will be offered to track important parameters and health indicators, which would facilitate the process of remote monitoring and enable patients to be more active in health care. Furthermore, telemedicine will continue to grow and bring an additional level of access to healthcare services, especially in underserved areas, and reduce healthcare disparities. This combination of the technologies will result in more efficient, effective and patient centred healthcare system.

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 - 7 Notification by CDSCO on classification of non-notified medical devices.
 - 8 MD Rules, First Schedule.
 - 9 CPA 2019, Section 87.
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 - 11 Section 3 of the SPDI Rules define 'Sensitive Personal Data or Information'
 - 12 Rule 2(1)(g) of the CERT-In Rules define “cyber incident”
 - 13 Rule 2(1)(h) of the CERT-In Rules define “cyber security incident”
 - 14 Section 2(x) of the DPDP Act defines “processing.”
 - 15 Any personal data processed for (i) for responding to a medical emergency involving a threat to the life or immediate threat to the health of the data principal or any other individual; or (ii) for taking measures to provide medical treatment or health services to any individual during an epidemic, outbreak of disease, or any other threat to public health, does not require prior consent but other requirements under the DPDP Act continue to apply.
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