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LEGAL AND REGULATORY FRAMEWORK FOR DIGITAL HEALTH – TELEMEDICINE PRACTICE GUIDELINES

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LEGAL AND REGULATORY FRAMEWORK FOR DIGITAL HEALTH – TELEMEDICINE PRACTICE GUIDELINES

In a significant move, the Ministry of Health and Family Welfare (“**MoHFW**”) on March 25, 2020 has issued the Telemedicine Practice Guidelines (“**Guidelines**”) for enabling Registered Medical Practitioners (“**RMPs**”) to provide healthcare using telemedicine. As per the Guidelines, ‘telemedicine’ is the delivery of health care services, where distance is a critical factor, by all the 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, all in the interests of advancing the health of individuals and their communities.

Prior to the introduction of these Guidelines, there were no specific or singular legislation or statutory guideline which dealt with the practice of telemedicine in India. The existing provisions under the Indian Medical Council Act, 1956, the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, Drugs and Cosmetics Act, 1940 and its subsequent rules thereunder, Clinical Establishment (Registration and Regulation) Act, 2010, Information Technology Act, 2000 and the Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011, primarily governed the practice of medicine and manner of preserving the personal information and records of the patients. The Department of Information Technology, Ministry of Communications and Information Technology had also issued the Recommended Guidelines & Standards for Practice of Telemedicine in India in the year 2003. As the name suggests, these guidelines were not binding. The existing provisions were neither exhaustive nor sufficient to address the concerns faced by the RMPs and the patients during telemedicine consultation (refer our earlier article on the issue¹).

To minimise this risk during telemedicine consultation and the current urgency due to COVID-19, the MoHFW approved the Guidelines, which would need to be followed by RMPs henceforth while providing telemedicine



consultation to patients. The Guidelines have been adopted as an amendment to the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 by adding regulation 3.8 titled as 'Consultation by Telemedicine'. In accordance with these regulations, the consultation through telemedicine by the RMPs under the Indian Medical Council Act, 1956 will be permissible in accordance with the Guidelines. The Guidelines in its scope covers the telemedicine consultations provided in India only.

Some of the key directives of the Guidelines are as under:

- i. **Identification of RMPs and Patient:** The telemedicine practice should not be anonymous and both, the RMP and the patient should know each other's identity. For fulfilling this requirement, the RMP should verify and confirm patient's identity by name, age, address, e-mail ID, contact number or any other identification as may be deemed appropriate by the concerned RMP. Further, before starting the consultation, the RMP should inform the patient about his/her name and qualifications and every RMP should display his/her registration number granted by the State Medical Council/National Medical Commission, on prescriptions, website or electronic communication.
- ii. **Patient Consent for Consultation:** While treating a patient through telemedicine, it is necessary to obtain the consent of the patient. The consent can be either implied or explicit depending on the situation, i.e. if the patient has initiated the telemedicine consultation, then the consent will be implied and if the RMP is initiating the telemedicine consultation then the consent will be explicit. The consent can be recorded either through e-mail, text or audio/video message and the said consent must be recorded in the patient's records.
- iii. **Types of Consultations:** The Guidelines prescribe for two types of telemedicine consultation, namely, first consult and follow-up consult.

The first consult means patient is consulting the RMP for the first time or the patient has consulted with the RMP earlier but there is a time gap of 6 (six) months in the previous consultation and the current consultation or the patient has consulted with the RMP earlier but for a different health condition.

The follow-up consult means the patient is consulting the same RMP again within a time period of 6 (six) months of his/her previous consultation and in continuation of care of the same health condition.
- iv. **Medical Prescription:** The Guidelines prescribe that the concerned RMP will prescribe the medicine to the patient only when the RMP is fully satisfied that he/she has gathered all the essential and relevant information about the patient's medical condition and medicines prescribed are in the best interest of the patient.

The Guidelines also impose certain limitations for prescribing medicines on telemedicine consultation and only a certain category of medicines can be prescribed to the patient via telemedicine consultation which includes:

- a) List O: It will comprise of those medicines which are safe to be prescribed through telemedicine. Under List O, the medicines which are used for common conditions and are often available 'over the counter' such as paracetamol, ORS, cough lozenges etc. will be included.
- b) List A: This list will include medicines which can be prescribed during the first consult which is a video consultation and can be re-prescribed for re-fill, in case of a follow-up.
- c) List B: This list will include medicines which RMPs can prescribe to their patient who is undergoing follow-up consultation in addition to those which have been prescribed during in-person consultation for the same medical condition.
- d) Prohibited List: The medicines listed in Schedule X of the Drugs and Cosmetics Act, 1940 or any narcotic and psychotropic substance listed in the Narcotics Drugs and Psychotropic Substances Act, 1985 will be included in the prohibited list and RMPs providing telemedicine consultation cannot prescribe medicines which falls under this list.

- v. **Medical Ethics, Data Privacy and Confidentiality**: Principles of medical ethics, including professional norms for protecting patient privacy and confidentiality as per the Indian Medical Council Act, 1956 will be binding and must be upheld and practiced. RMPs would be required to fully abide by the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 and with the relevant provisions of the Information Technology Act, 2000, data protection and privacy laws or any applicable rules notified from time to time for protecting patient privacy and confidentiality and regarding the handling and transfer of such personal information regarding the patient.

The urgency to implement the Guidelines may have been to address the unprecedented need for healthcare and consultation in the wake of COVID-19 outbreak and it may assist in dealing with the pandemic situation with safe distancing between the RMPs and the patients but in the long run it will also make healthcare more accessible and affordable with better maintenance of proper documentation and legal protection for both, RMPs and the patients.

Endnotes:

[1] <https://www.iltoday.com/2014/02/legal-position-concerning-telemedicine-in-india/>

Feedback

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