



ERGO

Analysing developments impacting business

TELEMEDICINE PRACTICE GUIDELINES

31 March 2020

[Background](#)

On 25 March 2020, the Board of Governors (in supersession of the Medical Council of India) have framed the Telemedicine Practice Guidelines (Guidelines) which are added as Appendix 5 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics Regulation 2002 (Ethics Regulations). It may be noted that the body of the Ethics Regulations do not seem to have been amended to include a reference to the new Appendix 5.

The Guidelines will be interpreted in conjunction to the other national clinical standards, policies, protocols and procedures.

It comes at a time when most of the world is struggling with the Covid-19 pandemic and India, which has a very low doctor to patient ratio, needs to efficiently deploy its healthcare professionals in the most efficient manner.

The background note in the Telemedicine Guidelines provides as follows:

“However, there has been concern on the practice of telemedicine. Lack of clear guidelines has created significant ambiguity for registered medical professionals, *raising doubts on the practice of telemedicine*. The 2018 judgement of the Hon'ble High Court of Bombay had created uncertainty about the place and legitimacy of telemedicine because an appropriate framework does not exist.”

[Purpose:](#)

In addition to taking benefit of technological advancements, the purpose of the Guidelines is inter alia to provide practical advice to the registered medical practitioners (RMP) and encourage the use of telemedicine as a normal practice.

[Stakeholders impacted:](#)

The Guidelines provide clarity to the stakeholders involved in the overall healthcare industry including the patients, the RMPs, hospitals, clinics, companies (including start-ups) providing online doctor consultation services, potential investors in such companies and the e-pharmacies who arrange for doctor consultation.

Exclusions:

Importantly, the Guidelines do not cover or provide for specifications for hardware or software, data management systems, use for conducting surgical or invasive procedures remotely, research and evaluation of healthcare workers and consultations outside India.

Compulsory training:

All registered medical practitioners intending to provide online consultation need to complete a mandatory online course within 3 (three) years of notification of the Guidelines. The Guidelines also mention "In the interim period, the principles mentioned in these guidelines need to be followed." While the term "interim" has not been defined or explained, it appears that the intent is to permit the RMPs to start using telemedicine immediately during the current pandemic.

Classification of Telemedicine applications:

The Guidelines classify the telemedicine applications on the basis of the following:

- Mode of Communication: Video, audio, text based, asynchronous;
- Timing of information transmitted: real time and asynchronous;
- Purpose of the consultation: First or follow up;
- Individuals involved: Whether the communication is between: (i) Patient to RMP, (ii) Caregiver to RMP, (iii) RMP to RMP, and (iv) health worker to RMP.

Technology:

Freedom has been given to RMPs to use any suitable tool for technology based consultation with patients such as telephone, video, devices connected over WAN or LAN, internet, etc. The Guidelines also explain the strengths and limitations of each mode of communication. Accordingly, the RMPs are required to decide the best mode of communication in the given situation.

Points to be considered for telemedicine consultation:

The Guidelines provide for the following seven points to be considered for practicing telemedicine:

- Telemedicine should be appropriate and sufficient as per context.
- RMP and patient should be identifiable, i.e., they should know each other's identity;
- Appropriate mode of telemedicine.
- Patient consent: If caregiver, health worker or RMP initiates telemedicine then explicit consent of the patient is required.
- Exchange of information for patient evaluation. RMP is required to collect all the necessary information from the patient to be able to exercise proper clinical judgment;
- Type of consultation (first consultation or follow up).

- Patient management: this covers health education, counseling and medication or prescribing medicines. As regards prescriptions, the Guidelines provide the following:
 - medicines may be prescribed only when RMP is satisfied with the medical condition as based on findings. Prescribing Medicines without an appropriate diagnosis/provisional diagnosis would amount to professional misconduct.
 - The Guidelines provide for categories of medicines that can be prescribed via tele-consultation which will be as notified in consultation with the Central Government from time to time. The categories of medicines that can be prescribed are listed below:
 - List O - Medicines which are safe to be prescribed.
 - List A - These medications are those which can be prescribed during the first consultation which is a video consultation and are being re-prescribed for re-fill, in case of follow-up.
 - List B: This is a list of medication which RMP can prescribe in a patient who is undergoing follow-up consultation in addition to those which have been prescribed during in-person consult for the same medical condition.
 - Prohibited List: An RMP providing consultation via telemedicine cannot prescribe medicines in this list. These medicine have a high potential of abuse and could harm the patient or the society at large if used improperly. This includes Schedule X drugs as well as drugs under Narcotic Drugs and Psychotropic Substances, Act, 1985.
 - Prescriptions should be made in accordance with the Ethics Regulations and the Drugs and Cosmetics Act and Rules. A sample prescription format has been provided in guidelines.
 - RMP should provide photo, scan, digital copy of a signed prescription or e-prescription to the patient via email or any messaging platform.
 - In case the RMP is transmitting the prescription directly to a pharmacy, he/ she must ensure explicit consent of the patient that entitles him/her to get the medicines dispensed from any pharmacy of his/ her choice.
 - The Board of Governors can modify this list.

The Guidelines have provided enough discretion to the RMPs on the use of telemedicine. This gives the doctor freedom to decide the required course of action on a case to case basis. However, it is also pertinent to note that in the event of any adverse issue, the decision of the doctor to use telemedicine can be questioned and this may subject the doctor and/or the institution to some risk.

- Various duties and responsibilities of RMPs has been provided. Penalties will be as per prevailing laws; and
- Record: RMPs are required to maintain digital trail or documentation of consultation.

Framework:

The following 5 situations have been covered under the Guidelines:

- Patient to RMP
- Caregiver to RMP
- Health Worker to RMP
- RMP to RMP
- Emergency Situations

Comments

- The Guidelines have come at a very apt time. Given the shortage of doctors and the highly contagious nature of the pandemic, the Guidelines will provide a lot more comfort to the doctors as they would have more clarity on their rights and obligations from a legal perspective.
- Understandably, the guidelines are subjective and provide discretion to the RMPs to decide whether telemedicine would be an appropriate method in each case.
- While training is required for every RMP, an interim waiver seems to have been provided to the RMPs in view of the prevalent situation caused by the Covid-19 pandemic.
- Hospitals, clinics and companies will need to ensure that their doctors receive the mandatory online training. It could involve additional compliance and costs.
- In addition to the Guidelines, the RMPs, hospitals, clinics and companies will need to comply with all other applicable requirements including data privacy obligations.
- The Guidelines do not dilute the duty of care by the RMPs.
- The Guidelines do not cover consultations involving doctors or patients outside India.

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