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TELEMEDICINE PRACTICE IN INDIA

“TELEMEDICINE PRACTICE GUIDELINES, 2020”

Telemedicine is emerging as an important tool for convenient as well as specialized healthcare, particularly for patients in remote locations with limited access to standardized healthcare services. Telemedicine services involve the transfer of medical information and expertise through telecommunication and computer technologies and aim to facilitate diagnosis & treatment of patients. Though the teleconsultation platforms would help to deliver widespread healthcare services, there are several concerns that exist about the medicolegal implications of telemedicine relating to registration, licensing, insurance, quality, privacy and confidentiality issues, as well as other risks associated with electronic health care communication.

Currently, the Telemedicine sector is governed by a set of scattered regulations. In the year 2018, the Bombay High Court in *Deep Sanjeev Pawaskar and Anr. v. State of Maharashtra* held two doctors liable for medical negligence in lieu of the medical consultation/ advice provided through telephonic medium. This judgment acted as a strong deterrent to the practice of telemedicine in India, with doctors being gravely concerned about the medico legal liability of such service.

On March 25, 2020, the Ministry of Health and Family Welfare (“**MoHFW**”) along with NITI Aayog issued the Telemedicine Practice Guidelines (“**Guidelines**”) that gave statutory support and basis for the Registered Medical Practitioners (“**RMPs**”) to practice telemedicine in India. An “RMP” under Indian Medical Council Act, 1956 is a person who is enrolled in the State Medical Register or the In Guidelines has been as defined:

“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”

Under the Guidelines the RMPs who intend to practice telemedicine will have to undertake a mandatory online course within 3 years of notification of the guidelines and shall uphold the same professional and ethical norms and standards as applicable to traditional in-person care, within the intrinsic limitations of telemedicine.

The Guidelines provide for following kinds of interactions: (a) patient to RMP, (b) caregiver to RMP, (c) health worker to RMP, (d) RMP to RMP and (e) emergency situations. Under the Guidelines Telemedicine applications have been segregated into four different types, based on – (a) mode of communication, (b) timing of the information transmitted, (c) the purpose of the consultation and (d) the interaction between the individuals involved.

The Guidelines suggest that telemedicine consultations should be treated the same way as in-person consultations. RMP shall issue a prescription as per the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations and 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. RMP may charge an appropriate fee for the Telemedicine consultation provided.

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GUIDELINES FOR RMP

UNDER THE TELEMEDICINE GUIDELINES

The Telemedicine Guidelines gives RMP the liberty of deciding which type of consultation is best suited for the patient. The RMP should exercise proper discretion and not compromise on the quality of care. They should follow 'Seven elements' before considering any telemedicine consultation -

1. **Context:** an RMP is to exercise his/ her professional judgment and discretion to determine whether the particular case being presented by the patient is appropriate for a telemedicine consultation or whether the same mandates an in-person consultation.
2. **Identification of RMP and Patient:** Telemedicine consultation should not be anonymous: both the patient and the RMP need to know each other's identity.
 - Patient's Identity-** An RMP should verify and confirm patient's identity by name, age, address, email ID, phone number, registered ID or any other identification as may be deemed to be appropriate.
 - RMP's Identity-** The RMP should introduce themselves and their qualification before starting the consultation. They should display the registration number accorded by the State Medical Council/National Medical Commission, on prescriptions, website, electronic communication and receipts etc. given to the patients.
 - Minor-** If minor they should be accompanied by an adult and proof of both should be available including relationship.
3. **Mode of Telemedicine:** The Guidelines categorize such modes into three major categories: video, audio or text.
4. **Patient Consent:** Patient consent is extremely crucial in any telemedicine consultation and the same may be express or implied. If the patient initiates the consultation then the consent is implied and if a health worker, caregiver or RMP initiates the consultation then the express consent of the patient is to be made known.
5. **Exchange of Information for Patient Evaluation:** The Guidelines give a framework of the kind of information that is to be sought from a patient, ultimately the onus is placed on the RMP to gather sufficient medical information about the patient's condition before making any professional judgment. The RMP is to also maintain records of such patient information.
6. **Types of Consultation:** The Guidelines segregate the types of consultations in two types – first consultation and follow-up consultation, and also lays down the ambit of the same.
7. **Patient Management:** if the RMP is of the opinion that the condition exhibited by the patient can be adequately managed by telemedicine then he/ she may (a) provide health education, and/ or (b) provide counselling of a particular clinical condition, and/ or (c) prescribe medicines.

On prescribing medicines, the Guidelines emphasize that the same is at the professional discretion of the RMP and would entail the same professional accountability as in traditional in-person consultation. The RMP can only prescribe drugs mentioned in Lists O, A and B and cannot prescribe medicines enlisted in the Prohibited List vide telemedicine consultation.



TELEMEDICINE - A VIABLE BUSINESS MODEL?

BALANCING BETWEEN THE UN-REGULATED & OVER-REGULATED

There are a lot of questions and lacunae which need to be addressed for growth of telemedicine as a viable business model in the healthcare sector in India. While addressing these, regulators must strike a balance and ensure that this sector is not unregulated or over regulated.

Registration of Establishments & Centers

Clinical Establishments (Registration & Regulation) Act 2010 ["CERRA"] governs all public and private sector clinical establishments (including single doctor clinics) and requires mandatory registration. The definition of Clinical Establishment under the CERRA is broad and would cover a center from which a service provider is providing telemedicine services (such as diagnostic services).

Where a service provider has obtained registration as a clinic under CERRA, it must comply with certain minimum infrastructure, equipment and bio-medical waste management requirements etc. A telemedicine model where only doctors are sitting at a center, providing advice to field doctors/nurses, compliance with such requirements would be needless, cumbersome and costly. However, non-compliance with the requirement to obtain registration and comply with its conditions would attract penalties (which may also be cancellation of registration) under CERRA.

In our view, it would be prudent for the government to recognize telemedicine as a distinct sector and have a consolidated registration process under which the service provider can provide a list of centers it has/will establish and give regular updates of any changes.

Registration of Medical Practitioners

Medical practitioners are required to get themselves registered with the State Medical Councils (SMCs). Upon receipt of the state medical registers and

verification (if required) by the Medical Council of India (MCI), names are included under the Indian medical register and such medical practitioners are then permitted to practice all over India. However, there are certain States which require medical practitioners to obtain registration with their State specific medical councils to practice in their specific States.

In the context of telemedicine, it is unclear whether a medical practitioner registered in one State will be permitted to provide services in another State without obtaining any additional registration. While the Ethics Committee of the MCI has stated that a medical practitioner is not required to obtain registration from more than one SMC, no amendment has been made to this effect under the Indian Medical Council Act.

Liability of Service Providers and Medical Practitioners

The liability of doctors (Primary Doctors) and field doctors/nurses/paramedics (Field Experts) under the Telemedicine model is yet to be tested in Indian courts. It would be beneficial if the legislature and/or courts prescribe principles compartmentalizing the liability of Primary Doctors and Field Experts.

In our opinion, liability of Primary Doctors must be limited to opinions they give and liability of the Field Experts must be determined based on how they deliver services (based on the opinions communicated by the Primary Doctors). Our regulatory regime should provide for separate standards for Primary Doctors and Field Experts.

DUTIES AND RESPONSIBILITIES OF RMP

MEDICAL ETHICS, DATA PRIVACY & CONFIDENTIALITY

Principles of medical ethics, including professional norms for protecting patient privacy and confidentiality as per the Indian Medical Council Act shall be binding and must be upheld and practiced.

Registered Medical Practitioner would be required to fully abide by Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 and with the relevant provisions of the IT Act, 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. This shall be binding and must be upheld and practiced.

Registered Medical Practitioners will not be held responsible for breach of confidentiality if there is reasonable evidence to believe that a patient's privacy and confidentiality has been compromised by a technology breach or by a person other than RMP.

The RMPs should ensure that reasonable degree of care is undertaken during hiring such services.

Misconduct is specifically noted that in addition to all general requirements under the MCI Act for professional conduct, ethics etc, while using

telemedicine all actions that wilfully compromise patient care or privacy and confidentiality, or violate any prevailing law are explicitly not permissible.

Some examples of actions that are not permissible:

- RMPs insisting on Telemedicine, when the patient is willing to travel to a facility and/or requests an in-person consultation
- RMPs misusing patient images and data, especially private and sensitive in nature (e.g. RMP uploads an explicit picture of patient on social media etc)
- RMPs who use telemedicine to prescribe medicines from the specific restricted list
- RMPs are not permitted to solicit patients for telemedicine through any advertisements or inducements

The Penalties for misconduct are as per IMC Act, Ethics Regulations and other prevailing laws.



SPECIFIC RESTRICTIONS

UNDER THE TELEMEDICINE GUIDELINES

There are certain limitations on prescribing medicines via telemedicine depending upon the type of consultation and mode of consultation. The categories of medicines that can be prescribed via tele-consultation will be notified in consultation with the Central Government from time to time. The categories of medicines that can be prescribed are listed below:

List O: It will comprise those medicines which are safe to be prescribed through any mode of tele-consultation. In essence they would comprise of 'over the counter' medications. For instance, these medicines would include, paracetamol, ORS solutions, cough lozenges etc

List A: These medications are those which can be prescribed during the first consult which is a video consultation and is being re-prescribed for re-fill, in case of follow-up. This would be an inclusion list, containing relatively safe medicines with low potential for abuse .

List B: 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 as these medicines have a high potential of abuse and could harm the patient or the society at large if used improperly. These include medicines listed in Schedule X of Drug and Cosmetic Act and Rules or any Narcotic and Psychotropic substance listed in the Narcotic Drugs and Psychotropic Substances, Act, 1985



ORDINANCE TO PROTECT HEALTHCARE WORKERS

The Union Government approved the promulgation of an ordinance to amend the Epidemic Diseases Act, 1897, making acts of violence against medical staff a cognizable and non-bailable offence and to provide compensation for injury to healthcare personnel or for damage or loss to property. The ordinance proposes that in cases of attacks on healthcare workers, the investigation will be completed within 30 days and the final decision arrived at within one year.

This ordinance has been precipitated by the precarious situation and the dire need for flawless health services during the COVID-19 pandemic.

The ordinance states that the acts of violence against doctors and other medical staff will be a cognisable and non-bailable offence. The punishment for such attacks will be 3 months to 5 years and the fine Rs. 50,000 to Rs. 2 lakh. In severe cases, where there are grievous injuries, the punishment will be 6 months to 7 years and the fine Rs. 1 lakh to Rs. 5 lakh. Such punishments will serve as a deterrent to unruly patients and their relatives, if found guilty.

There are, however, some major caveats to be kept in mind. The ordinance has been brought as an amendment to the Epidemic Diseases Act, 1897, and hence, may become infructuous after the pandemic is declared over.

CONCLUDING REMARKS

- These guidelines, will serve as an important tool to enable accessibility of healthcare services to the general masses of the country. Telemedicine could come as a great boon to India as its basic characteristics are quite well suited to deliver healthcare services across the large geographical expanse of the country.
- It should be borne in mind that the guidelines do not provide for consultations outside the jurisdiction of India. It does not cover hardware or software, infrastructure building & maintenance, data management systems; standards and inter operability, use of digital technology to conduct surgical or invasive procedures remotely. Hence, clear guidelines on issues of telemedicine across national borders will bring some clarity to the telemedicine practitioners.
- A Registered Medical Practitioner (“RMP”) under Indian Medical Council Act, 1956 is a person who is enrolled in the State Medical Register or the Indian Medical Register. Every practising doctor in India today is required by law to be enrolled in the State Medical Register or Indian Medical Register before the start of his or her medical practice. Therefore, the guidelines do not add any new requirement of registration for doctors who want to practice telemedicine and provide teleconsultation to his or her patients.
- The future challenges with respect to the Practice of Telemedicine could include : Standardization of equipment and teleservices with periodic checks and submission to a regulatory authority; Telemedicine laws for information storage and access; Equipment liability, maintenance and safety etc.
- Health insurance reimbursement for telemedicine consults in India will strengthen this form of practise

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