

SUGGESTED ROADMAP FOR LEGISLATIVE FRAMEWORK

In exercise of the powers conferred by of section 33 of The Indian Medical Council Act, 1956, the Medical Council of India, with the previous sanction of the Central Government makes the following regulations, namely:

Chapter I:

PRELIMINARY

1. Short Title, and Commencement

- 1) These rules may be called the Indian Medical Council (Telehealth) Regulations, 2020.
- 2) They shall come into force on the date of their publication in the Official Gazette.

2. Definitions

In this Act, unless the context otherwise requires:

- (1) "Act" means the Indian Medical Council Act, 1956.
- (2) "adjudicating body" means the Ethics and Medical Registration Board as established under Section 16 of The National Medical Commission Act, 2019.
- (3) "Health information" means any information, including genetic information, whether oral or recorded in any form or medium, that: (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, software application, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Explanation: this must be read with the relevant data protection laws; and must conform to the definition contained within the proposed data protection bill.

- (4) "teleconsult" means any interaction initiated by the patient or the designate caregiver, with his willingness and express consent to engage with the physician for the purposes of consultation through the use of information and communications technology.
- (5) "telehealth" means delivery of healthcare services by all healthcare professionals, where distance is a critical factor, through the use of information and communications technology to provide promotive, preventive, curative and rehabilitative healthcare services, research and evaluation, health administration services, and continuing education of healthcare providers. This definition shall include teleconsult, telemedicine and telecare.

Explanation: this definition acknowledges the usage of the terms "e-health", "digital health", "teleconsultation", "telemonitoring". This is inclusive of

Delivery of healthcare services by all healthcare professionals, where distance is a critical factor, through the use of ICTs, especially two-way interactive audio/video communications and telemetry systems to deliver healthcare services, mainly curative.

- (5) “telehealth practitioner” means any person, including but not limited to Medical Officers, Staff Nurses, Pharmacist, and Lab Technicians, who have direct or indirect interaction with a patient by virtue of their position within the healthcare delivery set up, in public and private domains.

Chapter II:

Adjudicating Body

3. Duties and Functions of the Adjudicating Body

Without prejudice to the other provisions of the National Medical Commission Act, 2019, the Ethics and Medical Registration Board shall have the following powers and functions:

1. Subject to the provisions of the Act, it shall be the duty of the Adjudicating Body to protect the interests of all stakeholders, including patients in India, and to promote the development of, and regulate the use of technology to provide healthcare services, by such measures as it thinks fit.
2. Without prejudice to the generality of the foregoing provisions, the measures referred to herein may provide for:
 - i. stipulating and regulating the standards of telehealth practice, and educational qualifications required for that purpose, including technical standards, directions to the concerned institutions and persons in order to implement and enforce these standards;
 - ii. regulating the work of any person involved in the practice of telehealth, either directly or indirectly, in any manner;
 - iii. maintaining adequate records of the practice rendered by each person practicing telehealth;
 - iv. regulating the standards of privacy of information obtained during the practice of telemedicine;
 - v. calling for information and records from any person who practices telehealth;
 - vi. performing such other functions as may be prescribed.
3. Without prejudice to the provisions contained in sub-section (2), the Adjudicating Body may, by an order, for reasons to be recorded in writing, in the interests of patients and the general provision of healthcare services, take any of the following measures, either pending investigation or inquiry or on completion of such investigation or inquiry, namely:
 - (i) prohibiting any person or institution from the practice of telemedicine; and

- (ii) placing restrictions on the level at which telehealth is practiced by any person or institution.

4. The Adjudicating Body shall –

- 1. adjudicate any dispute –
 - i. between two or more healthcare providers;
 - ii. between healthcare provider and infrastructure provider;
 - iii. between group of consumers/ patients and healthcare provider.

Provided that nothing in this clause shall apply in respect of matters relating to the complaint of an individual consumer maintainable before a Consumer Disputes Redressal Forum or a Consumer Disputes Redressal Commission or the National Consumer Redressal Commission. **[Reference to be made with respect to the applicable data protection laws.]**

- 2. hear and dispose of appeal against any decision, direction, or order of the State Medical Council under this Act.

Chapter III:

TELEHEALTH PRACTICE

5. **Interactions.**

- 1. Telecounseling. Any teleconsult whereby the telehealth practitioners provide general advice which *does not warrant dispensation of a prescription*, will be treated as a mere facilitative interaction between such physician and patient and is permissible.
- 2. Prescription of drugs. Any teleconsult whereby the physician provides advice and prescribes administration or intake of over the counter drugs [*insert reference to Drugs and Cosmetics Act/ Rules*] basis the interaction with the physician; and whereby such dispensation does not require physical examination of the patient is permissible.
- 3. Follow-up. Any teleconsult whereby the physician has met the patient seeking advice earlier in a face to face interaction, or has engaged in a telecounseling session, may proceed to prescribe drugs [*insert reference to Drugs and Cosmetics Act/ Rules*] without actual/physical examination of the patient. However, this is subject to the follow-up interaction having been initiated by the patient before the expiry of a finite time period, as prescribed by the Adjudicating Body.
- 4. Acute Emergency conditions. Any teleconsult which arises out of an acute condition of emergency, and whereby the call is initiated by the patient or the caregiver, the physician *may* choose to advise in good faith to protect and restore the vital interests of the concerned patient.
- 5. All the interactions identified at sub-clauses 1, 2, 3, and 4, are to be performed for altruistic reasons; with the willingness and express consent of the patient or the caregiver, as the case maybe; and, for the express benefit of the patient.
- 6. Any such advice given by the acting physician in good faith is permissible in law and will not be treated as illegal or an act to the detriment of the interests of the patient.

7. No physician will engage in any of the aforesaid interactions with the patient, where the ailment or complaint is of a nature which requires / mandates physical examination of the patient. For avoidance of doubt, in the event where the interaction has commenced, the physician must desist or cease such interaction, upon realizing that such ailments/ complaints require / mandate physical examination of the patient.

DUTIES AND LIABILITIES OF PERSONS PRACTICING TELEMEDICINE

6. Maintenance of Records

1. Every telehealth practitioner shall submit a periodical report to the Adjudicating Body, as and where such requirement is raised.
2. The contents of the report referred to in sub-section (1) shall include all requirements as per the requirements hereof.

Explanation: the same may be required to include security and audit measures, including a list of breaches, redressal mechanisms deployed, vulnerabilities, liabilities, etc.

7. Identification of Technology

1. In order to ensure adequate delivery of telehealth, persons practicing shall identify:
 - (i) all equipment (both hardware and software) used for telemedicine;
 - (ii) the owners and parties responsible for maintaining the equipment;
 - (iii) the format for transmitting medical information; and
 - (iv) the frequency and format of reports.

and maintain regular records of the same and furnish brief particulars thereof as part of the periodic report submitted to the Regulatory Body in accordance with Rule 5 above.

8. General Principle for liabilities of persons practicing Telehealth

1. Except as specifically provided in the Act, health care delivered through electronic means, regardless of form, shall be treated no differently from health care delivered face to face, directly between health care worker and patient.
2. All telehealth consultations in all set-ups, public and private alike, will have to be basis at least one face to face consultation between the physician and the patient. For the sake of clarity, teleconsultation without any face to face consultation is not permitted.

9. Determination of Doctor Patient Relationships

1. For the purposes of determination of liability in relation to provision to telehealth services, the following shall be considered:

- i. If the patient and the doctor practicing telehealth have had a direct interaction either in person or through audio, visual, or data communications;

Explanation - A conference call between the telemedicine doctor and the treating doctor will be considered to be a direct interaction between the patient and the telemedicine doctor.

2. The following factors (whether individually, or by a combination of two or more factors) shall be relevant for the determination of existence of a doctor patient relationship:
 - i. whether the doctor and the patient have met;
 - ii. whether the doctor examined the patient;
 - iii. whether the patient's records were viewed by the doctor;
 - iv. whether the doctor knows the patient's name;
 - v. whether the doctor was paid a fee;
 - vi. whether the patient has failed to follow the doctor's advice; and/or whether the doctor-patient interaction arose because of an emergency situation where the doctor was forced to treat the patient.

Identification of Doctor and Patients can be regulated, as is done in some countries. Email correspondence can also be regulated. Anonymous use of telehealth should not be allowed neither for doctors nor for patients regardless of the status.^{1s}

10. Physician – Physician Relationship

1. Referring physician must take all precautions in communicating the information pertaining to the patient to the specialist physician, in a manner which is legible, and is clear to the understanding of the specialist physician.
2. Referring physician must ensure that all records are accurately preserved, for the validation and confirmation of the specialist physician. Such validation mechanism may be prescribed by the Adjudicating Body, and may also provide for the technical and security standards to be complied with.

11. Duties of Physicians

1. Physicians shall adhere to the Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002.
2. The referring doctor shall take reasonable steps:
 - (i) to provide for safe storage and/or transmission of the patient's records by utilizing an adequate encryption system; and
 - (ii) restrict access to the technological set-up.
3. The referring doctor and the consulting/ telehealth doctor shall both be responsible to seek informed consent from the patient prior to prescribing, or administration of medicine.

¹CPME Guidelines for Telemedicine.

Explanation: "informed consent" shall have the same meaning as prescribed under the relevant data protection laws.

Chapter V:

PENALTIES

12. Penalties for other breaches

Penalties shall be prescribed in alignment with the existing laws, and regulations, including but not limited to the relevant provisions as under the Indian Penal Code, 1860, the Information Technology Act, 2000, law of torts.

The present rules shall add to the existing framework, and not repudiate the established governing bodies, statutory councils which have been instrumental in bringing major overhauls and fostering the practice of medicine in the country. The legislation should only aim at lending recognition and addressing the issue of insecurity and absolute lack of clarity amongst the stakeholders.