

PROVINCIAL ASSEMBLY OF SINDH
NOTIFICATION
KARACHI, THE 28TH DECEMBER, 2021

NO.PAS/LEGIS-B-35/2021-The Sindh Telemedicine and Telehealth Bill, 2021 having been passed by the Provincial Assembly of Sindh on 26TH November, 2021 and assented by the Governor of Sindh on 17TH December, 2021 is hereby published as an Act of the Legislature of Sindh.

THE SINDH TELEMEDICINE AND TELEHEALTH ACT, 2021.

SINDH ACT NO. XXXVI OF 2021

AN
ACT

to facilitate, enhance and improve access to healthcare through distant health platform and to ease the shortage of healthcare professionals.

WHEREAS it is expedient to facilitate health services and to promote Preamble distant technology-based access to health provisions in the Province of Sindh.

CHAPTER-I
PRELIMINARY

1. It is hereby enacted as follows:

- (i) This Act may be called the Sindh Telemedicine and Telehealth Act, Short title, extend 2021. and commencement
- (ii) It shall extend to the whole of the Province of Sindh.
- (iii) It shall come into force at once.

2. In this Act, unless there is anything repugnant in the subject or context:- Definitions

- (i) "caregiver" means a family member, or any person authorized by the patient to represent the patient":
- (ii) "consent" means consent given in writing or recorded by the patient or authorized caregiver initiates the telemedicine service. Consent is explicit when the RMP/Healthcare provider initiate telemedicine services.
- (iii) "health worker" means a Nurse, paramedic, LHV, LHW, CMW, FWw, FWC or an Allied Health Professional;
- (iv) "helpline" means a continuously managed technology platform for communicating with RMPs regarding any medical or other relevant issues;
- (v) "provisional diagnosis" means a diagnosis with a strong presumption that the full criteria shall ultimately be met for a disorder, but not enough information is available to make a firm diagnosis;
- (vi) "registered medical practitioner (RMP)" means a person who is registered with Pakistan Medical and Dental Council/Pakistan Medical

Commission as well as international Medical Providers (MDs) with valid clinical practice licenses as well as clinical care registered mid-level providers holding a certification for digital practice of medicine and is registered in a registry for imparting telemedicine or telehealth services. In addition, approved clinical care organizations and health systems with approved and registered clinical providers shall also be able to establish platform to provide telehealth services;

(vii) "registry" means to create and to maintain a database of RMPs and paramedics who want to practice Telemedicine and Telehealth;

(viii) "technology platform" means specific tools to be used for telemedicine or telehealth include systems with patient clinical information privacy protection using mobile, landlines with data linkage. Secure platforms include approved mobile apps and internet based digital platform for Telemedicine, Telehealth or Data Transmission systems. Irrespective of the tool of communication used, patient data and privacy of the patient care is the core principle of telemedicine practice carrying out by the use of approved technology platform for patient care, patient consultation or education, with patient privacy and data security as the highest priority as per the Health Insurance Portability and Accountability Act (HIPPA) Privacy Rules.

(ix) "teleconsultation" means consultation between clinical care providers including nurses, primary care providers especially care providers, dental as well as ancillary care providers with patients and/ or their primary caregivers;

(x) "telehealth" means imparting or continuation of education of healthcare providers through an online portal, all in the interest of advancing the health of individuals and their communities. Also, for the delivery and facilitation of health and health related services including medical care provider and patient education, health information services and _ self-care via telecommunication and or digital communication technologies;

(xi) "telemedicine" is defined as delivery of healthcare services through secure two way audio or video connections, including the application of secure video conferencing or store and forward technology, electronic media or other telecommunications technology, or an automated computer program including artificial intelligence including, but not limited to online adaptive interviews, remote patient monitoring devices by all healthcare professionals using information, communication technology for the exchange of information for diagnosis, treatment and prevention of diseases and injuries, and research and evaluation. It does not include an e-mail message, or facsimile transmission between the provider and the patient, as the delivery of healthcare services through secure audio and or audio-visual connections, by all the healthcare professionals using information and communication technology for the exchange of information for diagnosis, treatment and prevention of diseases and injuries, and research and evaluation;

- (xii) "tele mental health" means includes psychological support and consultation on psychiatric disorders and counseling;
- (xii) "Tele ophthalmology" means access to eye specialist for patients in remote areas, ophthalmic disease screening, diagnosis and monitoring;
- (xiv) "tele pathology" is use of technology to transfer image rich pathology data, between distant locations for the purposes of diagnosis, education, and research;
- (xv) "Telediagnosis" is the use of technology platform for the transmission of physical examination records, investigation reports and medical reports remotely or concurrently to a specialist at a different or the same geographical location; and
- (xvi) "teleradiology" means the ability to transmit radio-graphic images (X-rays, CT, MRI, PET or CT, SPECT or CT, MG, Ultrasound) from one location to another through technology platforms.

3. (1) A Registered Medical Practitioner (RMP) or Health Care Service Organization (HCSO), like hospitals and clinics entered into the registry shall provide Telemedicine consultation to patients from any part of Sindh Province.

(2) Registered medical practitioners shall be entitled to practice Tele Medicines or Tele Health after taking an online course on the practice of Tele Medicine and Tele Health and being registered in the registry. This course or training can be provided by online technology provider organizations as a part of implementation of telehealth platform.

(3) The Registered Medical Practitioner (RMP) shall inform the patient of his/her qualification by providing PMDC/PMC registration including area of specialization and number of years in the clinical practice within the provider profile on approved electronic telehealth platform. The RMP should ensure that there is a mechanism for a patient to verify the credentials and contact details of the RMP.

(4) Telehealth registered Health professionals shall give tele health services to any medical or paramedical professionals serving at any health facility and shall also give telehealth services to community, general public for promotion of good health practices and for information and education.

(5) A consent shall required to be submitted by the patient or authorized caregiver before telemedicine consultation is offered. An explicit consent shall be recorded in any form. Patient can send an email, text or audio/video message. Patient can state his/her intent on phone/video to the RMP. The RMP must record the same in his patient's records. RMPs using telemedicine shall uphold the same professional and ethical norms and standards as applicable to traditional in-person care, within the intrinsic limitations of telemedicine.

4. (1) Registered Medical Practitioner (RMP) shall practice telemedicine or telehealth via different modes of tele-technology including video, audio and text.

Prerequisites.

Platform

(2) RMP/HCSO shall ensure privacy and security of platforms to be used for protection of data, information, documents and any other material and should set up reasonable security practices and measures in collection and storage of personal data as per the Health Insurance Portability and Accountability Act (HIPPA) Privacy Rules.

(3) No data or information shall be shared without the consent of the patient or authorized caregiver. The RMP/HCSO shall be held responsible for breach of confidentiality, if there is reasonable evidence to believe that the patient's privacy, data, information, and confidentiality is compromised by technology breach by any person other than the RMP. Such breach of confidentiality will result in a penalty of Rs.100,000/- or punishment for the term of two years either or both.

(4) There may be situations where in order to reach a diagnosis and to understand context better; a real-time consultation shall be preferable. There can be conditions where an RMP shall require hearing the patient speak or to visually examine the patient to make a diagnosis. In such cases, RMP shall recommend an audio video consultation. Considering the situation, using his/her clinical judgment, an RMP shall decide the best technology to use, diagnose and treat.

5. (1) The RMP shall use professional judgment on whether to go for Telemedicine consultation or to go for an in personal consultation or a referral, keeping the patients interest paramount after taking a holistic view of the given situation.

(2) The RMP shall also consider the mode/technologies available and their adequacy for diagnosis before choosing to proceed with any Health education or counseling or medication.

(3) The RMP shall consider the complexity of patient's health condition. Every patient/case/medical condition may be different. The RMP shall uphold the same standard of care as an in-person consultation within the intrinsic limits of telemedicine.

6. (1) Video or Audio or e-mail or Text for exchange of relevant information for diagnosis, medication, health education and counseling shall be transmitted through telehealth and telemedicine services.

(2) Patient shall consult with an RMP for diagnosis and treatment of his/her condition or for health education and counseling.

(3) Transmission of Summary of patient complaints and supplementary data including images, laboratory reports and/or radiological investigations between stakeholders. Such data may be forwarded to different parties with the consent of the patient or caregiver, at any point of time and thereafter accessed as per convenience/need.

(4) Patients shall use this service for follow up consultation on his/her ongoing treatment, preferably with the same RMP/HCSO who prescribed the treatment in an earlier in-person consult.

Information
Transmission

7. (1) The RMP shall use his/her professional discretion to gather the type and extent of patient information (history or examination findings or investigation reports or past reports etc.) required to be able to exercise proper clinical judgment. However, all the information shall be kept in a secure manner, use of Electronic Medical Record (EMR) is highly encouraged.

(2) Information can be supplemented through conversation with a healthcare worker/provider and by any information supported by technology-based tools.

(3) If a physical examination is critical information for consultation, RMP should not proceed until a physical examination is be arranged through an in-person consultant.

(4) The RMP shall maintain all patient records including case history, investigation reports, images etc. as appropriate in a secure telehealth platform.

8. There would be no limitations to the consultation as needed by the patient. The patient may use this platform for reviewing lab results, initial consultation for basic non-urgent clinical care, follow-up consultation or specialty-based consultation. Nurses and other care providers may also provide consultation as a preventive care follow-up but not to provide clinical diagnosis or care services.

9.(1) Health Education: An RMP/Paramedic shall impart health promotion and disease prevention messages. These could be related to diet, physical activity, cessation of smoking, contagious infections, advise on immunizations, exercises, hygiene practice, mosquito control etc.

(2) Counseling: This is specific advice given to patients and it may, for instance, include food restrictions, do's and do not's for a patient on anticancer drugs, proper use of hearing aid, home physiotherapy, etc. to mitigate the underlying condition. This shall also include advise for new investigation that needs to be carried out before the next consultation.

10. (1) Prescribing medicines via telemedicine consultation is at the professional discretion of the RMP, it entails the same professional accountability as in the traditional in person consultancy. However, the provider would ensure to document all the medication provided and ensure pain management and control substance medication other than narcotics and psychotropic drug is prescribed after detail clinical evaluation and documentation.

(2) The RMP shall prescribe medicines via telemedicine only when RMP is satisfied that he/she has gathered adequate and relevant information regarding the patients' medical condition and prescribed medicines are in best interest of the patient (Prescribing medicines without an appropriate diagnosis/provisional diagnosis shall amount to a professional misconduct).

(3) The category of medicines that can be prescribed via tele-consultation shall be as notified in consultation with DRAP registered drugs:-

(i) It shall comprise of those medicines which are safe to be prescribed through any mode. Medicines which are used for common conditions and are often available over the counter for instance these medicines shall include, paracetamol, ORS Solution, Cough Lozenges etc;

Consultation

Health Education
and Counseling

Prescribing
Medication

(ii) Those medications which are being re-prescribed for refill, in case of follow-up there would include relatively safe medicine with low potential for abuse. Or shall be those medicines prescribed during in person consult for the same medical condition;

(iii) Medicines which cannot be prescribed are those with a high potential of abuse and/or could harm the patient including narcotics and psychotropic substances.

(4) If an RMP has prescribed medicines, RMP shall provide photo, scan, digital copy of a signed prescription or e-prescription to the patient via e-mail or any other 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 medicine dispensed from any pharmacy of his/her choice.

11. (1) Principles of medical ethic include professional norms for protecting patient privacy and confidentiality.

(2) The RMP/HCSO shall provide relevant provisions for data protection.

(3) Misconduct associated with Telemedicine would include:-

(i) willfully compromises patients care, privacy and confidentiality or violates any prevailing law;

(ii) insisting on telemedicine by rules when a patient is willing to travel to a facility and/or request in person consultation;

(iii) misusing of patient's images and data, especially private and sensitive in nature by the RMP/HCSO; and

(iv) to solicit patients for Telemedicine through any advertisements or inducement without permission by the RMP/HCSO.

12. There shall be two possible settings:-

(1) Patient is present with the caregiver during consultation and the caregiver has the consent approval of the patient.

(2) Patient is not present with the caregiver during consultation. This shall be the case where the patient is a minor or the patient is incapacitated for e.g. in medical conditions like dementia or physical disability or where the formal authorization or verified document establishing his relationship with the patient for consultation.

13. This shall cover interaction between health worker seeking consultation for a patient in a public or private health facility, can also include health camps, home visits, mobile medical units or any community-based interaction:-

(i) Health worker initiates and facilitates the telemedicine consultation on the premise that the patient has been seen by the health worker and has obtained an informed consent from the patient;

Consultation
between Patient and
RMP through
caregiver

Consultation
between Health
worker and RMP

(ii) Health worker must give detailed explanation of the health problems to the RMP which can be supplemented by additional information by the patient if required;

(iii) RMP may advise some additional laboratory or radiological tests for patient or indicate if appropriate for management via telemedicine;

(iv) Health worker shall communicate the underlying health condition of the patient to the RMP. He/she should seek advice for first aid for immediate relief and guidance for referral of patient as deemed necessary.

14. (1) RMP might use telemedicine services to consult with another RMP or specialist for a patient under his/her care. Such consultation can be initiated by RMP on his/her professional judgment.

(2) RMP asking for RMP/Specialist's advise remains the treating RMP and shall be responsible for treatment and other recommendations given to the patient.

15. In all telemedicine consultations, as per the judgment of the RMP, if it is an emergency situation, the goal and objective should be to provide in-person care at the soonest. However critical steps could be lifesaving and guidance and counseling could be critical. The guidelines are designed to provide a balanced approach in such conditions. The RMP, based on his/her professional discretion may:-

- (a) advise first aid
- (b) counseling
- (c) facilitate referral

In all cases of emergency, the patient must be advised for an in-person interaction with a Registered Medical Practitioner at the earliest.

16. Government may make rules and regulations for carrying out the purposes of this Act.

17. The provision of this Act shall have effect notwithstanding anything contrary contained in any other law, for the time being enforced.

18. If any difficulty arises in giving effect to the provisions of this Act, government may, by order published in the official gazette, make such provisions not inconsistent with the provisions of this Act, as appear to be necessary or expedient for removing such difficulty.

BY ORDER OF THE SPEAKER

PROVINCIAL ASSEMBLY OF SINDH

G.M.UMAR FAROOQ
SECRETARY

PROVINCIAL ASSEMBLY OF SINDH

Registered Medical
Practitioner to
another

RMP?/Specialist

Emergency
Situation

Power to make rules

Overriding effect

Power to remove
difficulties