

**Annex attached to Cabinet Resolution No. (40) of 2019
Concerning the Executive Regulations of the Federal Decree-Law No.
(4) of 2016 Concerning Medical Liability**

Rules & Conditions for Providing Telehealth services

First: Definitions

Remote Medical Consultation: A type of medical consultation provided by means of information and communication technologies, to give advice on the best ways to deal with the health case and takes place between a doctor and another doctor or a doctor and a patient, in cases where the doctor and the patient do not exist at the same place.

Remote Prescription: When the competent doctor prescribes medications, in cases where the doctor and the patient do not exist at the same place, by means of information and communication technologies, after a remote diagnosis is conducted and without clinical examination of the patient, or remote prescription of medication based on a diagnosis made through the conventional clinical manner.

Remote Diagnostics: Identifying the nature of the disease or health case of the patient, through the use of information and communication technologies by the health service provider.

Remote Patient Monitoring [RPM]: Obtaining vital signs and monitoring the patient's condition, through the use of information and communication technologies by the health service provider.

Remote Medical Intervention: Any remote medical intervention action through the use of information and communication technologies.

Second: Rules and Conditions for Providing Telehealth Services

- **General Rules:** They apply to all areas of providing telehealth services.
 1. Rules relating to the Facility that provides telehealth services:

The facility providing telehealth services shall abide by the following:

 - a. Obtain a license from the Health Authority allowing it to provide such services.
 - b. Provide a well-rounded technical network that ensures the proper provision of telehealth service, according to the standards set by the Health Authority.
 - c. Provide an adequate bandwidth.
 - d. Provide alternative ways for communication between the service provider and recipient.
 - e. Provide a backup power supply system.
 - f. Provide Servers within the State to store and record the information and a backup.
 - g. Provide cutting-edge internet technologies and systems that satisfy the requirements of the providing telehealth services.
 - h. Comply with high quality standards regarding telephone and call recording systems.
 - i. Provide the necessary technical equipment to register and document the healthcare service remotely provided.
 - j. Provide high-caliber qualified human resources to provide telehealth service, by making them undergo a special training that is in line with the nature of remotely provided healthcare service, including training on technical, technological and legal aspects as determined by the Health Authority in this regard.
 - k. Provide an insurance coverage for medical malpractice arising from or due to the provision of such service.
 - l. The working system adopted by the Facility shall satisfy the following requirements:

- 1) Provide evidence on the existence of a system for monitoring, overseeing and reporting the quality and safety of performance measures.
- 2) Provide the necessary means to maintain and document full records and data of persons receiving the telehealth service.
- 3) Provide a system to protect the data and records of the telehealth service, and allow only the authorized persons to access thereto.
- 4) Provide the necessary mechanisms to protect the privacy of persons receiving the telehealth service.
- 5) Develop a system to maintain the confidentiality of patients' files.
- 6) Develop manuals and procedures to regulate the provision of telehealth services, defining the roles and responsibilities within a governance system.
- 7) Develop a system for identifying the person receiving the telehealth service, and the necessary relevant documents as determined by the Health Authority.
- 8) Rules relating to Service Recipient:

Telehealth service recipients shall abide by the following instructions:

- m. Give consent to audio, video and other forms of recording.
- n. Agree to receive the service.
- o. Introduce himself /herself and give correct and complete information.

- **Special Rules:** They are the rules relating to each of the healthcare services remotely provided, on a case-by-case basis, according to the following:
 1. Rules on Remote Diagnostics Service:
 - a. The service shall be provided after an agreement is concluded between the service applicant and service provider, defining the procedures and methods of dealing between the two parties in this respect.
 - b. The following patient safety rules shall be observed:

- 1) The service must be provided by a diagnostic center duly licensed in the State.
- 2) Enable the Service Provide to access to the patient's previous medical images and related reports, for the sake of achieving accurate diagnosis and drawing up the necessary report.
- 3) Enable the Service Provider to obtain all correct patient-related data before its report is drawn up.
- 4) Easy communication with the doctor who drew up the remote diagnosis report, through the phone or any other means of communication available, so as to discuss the report whenever needed.

c. The following rules on the exchange of data and reports shall be observed:

- 1) Obtaining the patient consent before referring his / her data to any other Medical Facility for the sake of conducting remote diagnosis.
- 2) Referral of the data shall be made within the limits required by the patient's health case, and in a manner that ensures the completion of remote diagnosis as optimally as possible.
- 3) Establish precise procedures on how to transfer, archive, store, protect and maintain the confidentiality of the patient's data.

2. Rules on Remote Consultation Service:

Remote consultation shall be subjected to the relevant rules established by the Health Authority. In all cases, the health professional who deals directly with the patient shall be responsible for any healthcare work provided to the patient.

3. Rules related to Remote Prescription:

- a. Medications shall be remotely prescribed by a doctor duly licensed by the Health Authorities in the State and working at a Health Facility duly licensed to provide telehealth services.

- b. The doctor who remotely prescribes the medications shall examine the patient electronically, using e-technology, while adhering to the relevant standards for the level of healthcare within the State.
- c. Files and documents shall be documented in accordance with applicable rules and regulations.
- d. The prescription of medications shall be the result of a diagnosis that ensures that there are no impediments to prescribing and receiving the medications. It is also important to ensure that the patient is able to understand the risks and is well-aware of the benefits associated with the medication; otherwise, the patient should be referred to a healthcare doctor for clinical examination.
- e. The doctor shall discuss the treatment plan with the patient, unless the latter's physical or mental condition so prevents.
- f. Medications shall be prescribed in accordance with the applicable legislation in the State.
- g. The doctor may prescribe the medications without adhering to the remote prescription rules related to the diagnosis, and discuss the medications with the patient in the following cases:
 - 1) If consultation is made with another doctor having direct relationship with the patient, while providing continuing supervision of the treatment.
 - 2) Work shift case or by telephone coverage, so that the doctor who prescribes the medication has reviewed the patient's health records.

4. Rules on Telehealth Monitoring:

- a. Submitting a complete application to install and activate the Telehealth Monitoring Service at the home or the place where the patient (the client) exists.
- b. Submitting a Telehealth Monitoring Service application or order signed and dated by the treating doctor of the patient (client).

- c. Ensuring that the Telehealth Monitoring data are collected reliably and accurately.
- d. Data shall be stamped with the date and time to protect them from alteration.
- e. Ensuring that the monitoring data are documented in the patient's electronic medical records (EMR).
- f. The patient's clinical data may not be re-monitored by any other service provider.
- g. Maintaining the system documents and use of information.
- h. The data shall be reviewed by the nurse or the assistant doctor, and each of them shall be responsible for reporting the data to the doctor, and the latter shall issue the prescriptions.
- i. Submitting the periodic reports on the patient's data to the doctor.
- j. The patient shall be entitled to suspend the Telehealth Monitoring Service from home at any time.
- k. Telehealth monitoring service providers shall be available around the clock.
- l. The Telehealth Monitoring service includes the number of times, the type of monitoring, the timing and method of obtaining and transferring the data (e.g., are the results of the blood glucose check are uploaded on daily, weekly basis or immediately.....?).
- m. Determining the time of expected response to the patient's data.
- n. Determining off-working hours coverage policy for uploading the data and using the automated alarm system.
- o. Actions for dealing with "undesirable events" shall be established and made available to the persons concerned.
- p. The monitoring standards for manual and electronic analysis shall be provided both separately and jointly.
- q. Ensuring that all Telehealth Monitoring devices are functioning properly.

- r. Sensors may not cause any damage or irritation to the patient's skin, nor cause sleep distress or form a risk if swallowed.
 - s. Establishing the protocols of response to alarms received from the Telehealth Monitoring system.
 - t. Providing and maintaining Telehealth Monitoring equipment, which is the responsibility of the homecare provider or hospital.
5. Rules relating to Remote Medical Intervention:
- a. Remote medical intervention is subject to the relevant rules established by the Health Authority.
 - b. In all cases, there must be a health professional alongside the patient, who is able to intervene whenever needed in case of malfunctioning of remotely operated technical devices.