

Kingdom of Saudi Arabia



**National Health Information Center(NHIC)  
in Saudi Health Council (SHC)**

**Telemedicine Regulations in the Kingdom of Saudi Arabia**

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## Regulations Approval Process

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## LIST OF ACRONYMS

<b>AI</b>	Artificial Intelligence
<b>CBAHI</b>	Saudi Central Board for Accreditation of Healthcare Institutions
<b>CCHI</b>	Council of Cooperative Health Insurance
<b>HCP</b>	Healthcare Professional
<b>ICD</b>	International Classification of Diseases
<b>ICT</b>	Information and Communication Technology
<b>NHIC</b>	National Health Information Center
<b>RPM</b>	Remote Patient Monitoring
<b>SCFHS</b>	Saudi Commission for Health Specialties
<b>SFDA</b>	Saudi Food and Drug Authority
<b>SHC</b>	Saudi Health Council
<b>SMO</b>	Patient-requested second medical opinion
<b>STUE</b>	Saudi Telemedicine Unit of Excellence
<b>TLA</b>	Tele-assistance
<b>TLC</b>	Teleconsultation
<b>TLC1</b>	Teleconsultation Type 1
<b>TLC2</b>	Teleconsultation Type 2

# 1. INTRODUCTION

## 1.1 DOCUMENT PURPOSE

This document contains the regulations and supporting definitions that support the practice of telemedicine in the Kingdom of Saudi Arabia.

## 1.2 SCOPE

### 1.2.1 In Scope:

The scope of this document is the specification of requirements for telemedicine practice in the Kingdom of Saudi Arabia.

Telemedicine should be provided for: a) the purpose of screening, b) medical regulation (triage), c) consultation, d) diagnostics, e) the requirement of a medical opinion from a healthcare professional (HCP), f) support of the provision of treatment, and g) monitoring a medical condition.

### 1.2.2 Out of Scope:

The contents and specifications that are explicitly out of scope for this document are:

- Operational procedures that conform to the regulations.

## 1.3 STAKEHOLDERS IMPACTED BY THE DOCUMENT

The stakeholders impacted by the document are healthcare professionals, health facilities, health administration including Saudi Food and Drug Authority (SFDA), health insurances and telemedicine service or solution providers.

## 1.4 HOW TO READ THIS DOCUMENT

### 1.4.1 Where to Find Information

This document contains two normative sections. The document is structured as follows:

**Section 1:** contains an introduction to the *Regulations Set* document. This section contains a summary of the document purpose and scope, as well as other content to help orient a first-time reader to the topic of the document.

**Section 2:** specifies the regulations as defined for telemedicine.

### 1.4.2 Document Conventions

Throughout this document the following conventions<sup>1</sup> are used to specify requirement levels:

**SHALL:** the definition is an absolute requirement of the specification.

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<sup>1</sup> Definitions based upon RFC 2119

**SHALL NOT:** the definition is an absolute prohibition of the specification.

**SHOULD:** there may exist valid reasons in certain circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.

**SHOULD NOT:** there may exist valid reasons in certain circumstances where a particular behavior is acceptable or even useful, but the full implications should be understood, and the case carefully weighed before implementing any behavior described with this label.

**MAY or OPTIONAL:** means that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because the vendor feels that it enhances the product while another vendor may omit the same item.

## **2. KINGDOM OF SAUDI ARABIA TELEMEDICINE REGULATIONS ARTICLES**

### **2.1 DEFINITIONS**

- 2.1.1.** Telemedicine shall be defined as a remote medical practice using information and communication technology (ICT).
- 2.1.2.** Telemedicine shall be synchronous (simultaneous transfer of information including videoconference) or asynchronous (non-simultaneous transfer of information).
- 2.1.3.** Telemedicine should be delivered through video, and/or audio, and/or picture, and/or text, and/or data.
- 2.1.4.** Telemedicine should be used for an interaction between a patient and a HCP, or between two or more HCPs.
- 2.1.5.** Telemedicine should be used between an originating site and a distant site. The originating site is where the patient is located, and the distant site is where the remote HCP is located.
- 2.1.6.** Telemedicine may involve robots or artificial intelligence (AI).

### **2.2. CLASSIFICATION**

- 2.2.1.** Teleconsultation (TLC) is a remote medical consultation, which may occur in two types. Type 1 is between a patient and a HCP (TLC1) and type 2 is between two or more HCPs (TLC2).
- 2.2.2.** Teleconsultation between two or more HCPs (TLC2) is a remote primary or secondary medical opinion provided by a requested HCP to a requiring HCP.
- 2.2.3.** Teleconsultation is not limited to synchronous video consultation, but cannot be only audio.
- 2.2.4.** Remote patient monitoring (RPM) is the remote medical monitoring of a patient based on the medical and/or health data collected by a patient or a HCP.
- 2.2.5.** Tele-assistance (TLA) is the synchronous remote medical support provided by a HCP to assist another HCP to perform a medical activity.
- 2.2.6.** Patient-requested online second medical opinion (SMO) is the remote medical opinion requested by a patient to a HCP, to ask for a medical opinion other than the medical opinion provided by a previous HCP.

## **2.3. GENERAL CONSIDERATIONS**

- 2.3.1.** Telemedicine may be practiced by all types of accredited HCPs.
- 2.3.2.** All legal requirements applied to a HCP in the Kingdom of Saudi Arabia shall be applied to the practice of telemedicine.
- 2.3.3.** HCPs shall be allowed to practice telemedicine across all types of public healthcare providers in the Kingdom of Saudi Arabia and shall not be restricted to public or private sectors.
- 2.3.4.** HCPs practicing telemedicine and telemedicine service providers may be remunerated for the practice of telemedicine.
- 2.3.5.** Health insurance may include coverage of telemedicine activities in their contracts.
- 2.3.6.** Private health insurance shall provide coverage of telemedicine activities with at least a parity of public coverage and funding in telemedicine activities.
- 2.3.7.** Health insurance coverage of telemedicine activities shall be applied in accordance with the regulations on health insurance coverage of the Council of Cooperative Health Insurance (CCHI) in the Kingdom of Saudi Arabia.

## **2.4. IMPLEMENTATION**

- 2.4.1.** A regulating unit called the Saudi Telemedicine Unit of Excellence (STUE) shall be created within the National Health Information Center of the Saudi Health Council to lead, support, monitor and evaluate the implementation and development of telemedicine in the Kingdom of Saudi Arabia.
- 2.4.2.** Annual communication shall be provided and/or organized by the STUE to communicate publicly about the status of implementation and impact of telemedicine in the Kingdom of Saudi Arabia.

### **3. ORGANISATION OF A TELEMEDICINE ACTIVITY**

#### **3.1. BEFORE A TELEMEDICINE ACTIVITY**

##### **Training**

- 3.1.1.** HCPs shall be trained on telemedicine before practising telemedicine.
- 3.1.2.** HCP training on telemedicine may be provided during the initial health education or acquired with continuous education training in telemedicine accredited by the Saudi Commission for Health Specialties (SCFHS).
- 3.1.3.** The continuous education training shall be, at least, a continuous medical education training including an evaluation and may be a certificate training.
- 3.1.4.** The training program shall include content on telemedicine practice and regulations, content on telemedicine applied to registered specialties of the HCP, and to the use of telemedicine solutions, if necessary.
- 3.1.5.** Initial education of a HCP, including the medical residency curriculum, and healthcare facility managers education shall include telemedicine.

##### **Malpractice insurance**

- 3.1.6.** The malpractice insurance of HCPs practising telemedicine shall fall into their malpractice insurance.

##### **License and accreditation**

- 3.1.7.** An entity providing telemedicine services which is not licensed as a healthcare facility in the Kingdom of Saudi Arabia shall obtain a license to be allowed to practice telemedicine.
- 3.1.8.** All legal requirements applied to a healthcare facility shall be applied to an entity providing telemedicine services, including mandatory accreditation by the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI).
- 3.1.9.** A healthcare facility accreditation by CBAHI shall include criteria for telemedicine.

##### **Declaration**

- 3.1.10.** HCPs practising telemedicine in the Kingdom of Saudi Arabia shall declare themselves to the STUE through an online form and shall update this declaration annually.
- 3.1.11.** HCPs registered or licensed in another country, according to their country's regulations, shall be registered in the Kingdom of Saudi Arabia to provide telemedicine services in the Kingdom of Saudi Arabia. HCPs who do not reside in the Kingdom of Saudi Arabia remain accountable for their competence and actions to the authorities in the jurisdiction that governs their practice.
- 3.1.12.** Healthcare facilities providing telemedicine services shall declare their telemedicine activities to the STUE before initiating the activity and shall update this declaration annually.
- 3.1.13.** A declaration by a healthcare facility to the STUE shall include the description of their clinical objectives and model of care, financial model, telemedicine solution provider, and evaluation protocol based on a template defined by the STUE.

### **Agreement for collaboration**

- 3.1.14.** Contracting with a telemedicine solution provider shall be made after the description of the clinical objectives and model of care of the telemedicine activity and based on criteria defined by the STUE.
- 3.1.15.** If two or more healthcare facilities provide a collaborated telemedicine service, written agreements based on a template provided by the STUE shall be signed to formalize the relationship between both organizations.
- 3.1.16.** Medical devices used for telemedicine shall abide by the medical devices regulation under the umbrella of Saudi Food and Drug Authority. If a type of medical device used for telemedicine is not included into the existing medical devices regulations, a support from STUE should be required.

### **Health information**

- 3.1.17.** The practice of telemedicine shall be compliant with the health information exchange policy (SeHE) in the Kingdom of Saudi Arabia, including all relevant data security and privacy requirements, and be compliant with interoperability frameworks and/or HIPAA.
- 3.1.18.** HCPs shall have sufficient evidence to identify the patient for a telemedicine encounter.
- 3.1.19.** HCPs shall have access to all relevant patient health and medical information to practise telemedicine, if existing.

### **Patient rights**

- 3.1.20.** An informed consent shall be signed by a patient, preferably online, before the practice of any telemedicine activity.
- 3.1.21.** An informed consent signed by an inpatient shall be valid for the duration of the stay in the health facility.
- 3.1.22.** Patients shall be given the right to refuse and/or cancel any participation to a telemedicine activity, at any time, without the need to provide justification.
- 3.1.23.** Patients may issue a complaint about a telemedicine service, which shall be shared with the STUE for quality assurance purposes.
- 3.1.24.** Patients should receive relevant education on telemedicine, if deemed necessary by the HCP practising a telemedicine activity.

## **3.2. DURING A TELEMEDICINE ACTIVITY**

- 3.2.1.** HCPs practising telemedicine shall respect their obligations and ethical responsibilities.
- 3.2.2.** HCPs practising telemedicine shall respect and ensure medical confidentiality.
- 3.2.3.** HCPs practising telemedicine shall respect legal requirements for paediatric patients and patients with mental health conditions.
- 3.2.4.** A protocol shall be defined in case of technical incidents ceasing a telemedicine activity.
- 3.2.5.** A protocol shall be defined in case of a medical emergency.
- 3.2.6.** All patient health data and information shall be included into the medical record of a patient, which should be a medical record included into the telemedicine solution or electronic health record of the health facility.
- 3.2.7.** A HCP practising telemedicine may deliver an online prescription or medical investigation, which shall abide to the medical prescription and investigation regulations applied in the Kingdom of Saudi Arabia.
- 3.2.8.** A HCP shall be responsible for the prescription and/or medical investigation delivered in accordance with professional responsibility.
- 3.2.9.** A HCP shall prepare a referral in accordance with regulations on patient referrals in the Kingdom of Saudi Arabia, if deemed necessary, during a telemedicine activity.
- 3.2.10.** During a TLC2, the responsibility both HCPs shall engage and share their responsibility based on their individual contribution.

## **3.3. AFTER A TELEMEDICINE ACTIVITY**

- 3.3.1.** All telemedicine activities shall be included into the medical record of a patient.
- 3.3.2.** Telemedicine activities included in the medical record of a patient shall include: a) the provider identification, b) the location, c) date and time, d) type of telemedicine activity provided, e) details of the prescriptions and/or medical investigation provided, f) all technical incidents which may impact the telemedicine activity, and g) all adverse events which may be observed during the telemedicine activity.
- 3.3.3.** Medical coding, including the International Classification of Diseases (ICD), may be applied at the end of each telemedicine activity, in accordance with the medical coding regulations in the Kingdom of Saudi Arabia.
- 3.3.4.** Telemedicine service providers shall provide an online annual evaluation report to the STUE based on a template defined by the STUE.
- 3.3.5.** Telemedicine service providers may be inspected, at any given time, without prior notice in accordance with national regulations in the Kingdom of Saudi Arabia.