



وزارة الصحة
Ministry of Health

Clinical Governance Directorate – DHCOE
Legal Regulations for Telehealth Services

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Ministry of Health-Saudi Arabia

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الرقم : ٢٢٢٢٨٦٧
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المملكة العربية السعودية
وزارة الصحة
الإدارة العامة للشؤون القانونية
إدارة الاستشارات واللوائح

المحترم

سعادة مساعد معالي الوزير

السلام عليكم ورحمة الله وبركاته...

إشارة إلى إحالة سعادتكم رقم ٢٢٢٢٨٦٧ - ١٤٤٢ وتاريخ ١٢/٢٣/١٤٤٢ هـ بطلب الإفادة وابداء
الراي حيال النسخة المرفقة من القواعد التنظيمية لخدمات الطب الاتصالي.
نفيد سعادتكم أنه بعد الاطلاع والدراسة على القواعد التنظيمية لخدمات الطب الاتصالي وجد
بعض الملاحظات في الفقرة (٦) "متطلبات العاملين في مجال الرعاية الصحية" الفقرة (٤) . كما أنه
لم يتضح من هي الجهة المسئولة عن إصدار تراخيص خدمات الطب الاتصالي.
وقد وتم عقد اجتماع مع مركز تميز الصحة الرقمية والإدارة العامة لتراخيص المؤسسات الصحية
الخاصة لمناقشة هذه الملاحظات وتم اجراء التعديلات اللازمة على مشروع القواعد التنظيمية.
وبناء على ما سبق فإنه لا يوجد لدى هذه الإدارة ملاحظات حيال مشروع القواعد التنظيمية
لخدمات الطب الاتصالي.

وتقبلوا سعادتكم أطيب تحياتي ...

١٢/١٣

مدير عام الإدارة العامة للشؤون القانونية

منتعب بن حمد الأحمد

Abstract

The Royal Order (no. 47455) issued on 9/8/1441 AH, makes an exception to the provisions of Article 13 of Law of Practicing Health Professions issued by Royal Decree No. (M/59) on 4/11/1426 AH, that the health practitioner may conduct examinations or treatment through the services of telehealth in homes and workplaces, in accordance with the regulations set by the Ministry of Health. Accordingly, these regulations are made pursuant to the direction to the Ministry of Health to set the regulations relating to telehealth.

1. Definitions

(1) The following words and phrases, unless the context otherwise requires, shall have the following meanings:

(a) Credentialing is the process of obtaining, verifying, and assessing the qualification of a health care professional to provide care or services in or for a health care facility.

(b) Health care facility is an institution or an organization licensed to provide health care diagnosis and treatment services within the Kingdom of Saudi Arabia.

(c) Health care professional is an individual licensed to provide health care diagnosis and treatment or services related thereto within the Kingdom of Saudi Arabia and includes physicians, dentists, nurses, and other health practitioners licensed to practice the health profession in accordance with Law of Practicing Health Professions.

(d) Ministry of health is the Ministry of Health of the Kingdom of Saudi Arabia.

(e) Permitted telehealth services are the services allowed to be provided as a telehealth service within the scope of the facility's license and includes clinical services.

(f) Privileging is the process by which a specific scope and content of a patient care services are authorized for a health care professional by a health care facility based on the individual's credentials and performance.

(g) Tele-assistance is the use of telecommunications technology to give support or aid to a patient or another health care professional and it includes the synchronous remote medical support provided by a health care professional to assist another health care professional to render a medical service.

(h) Tele-consultation is the use of telecommunications technology to meet a doctor who is specially trained to advise the patient or other doctors about an illness or its treatment and includes remote medical opinion requested by a patient to a health care professional and seeking of medical opinion other than the medical opinion provided by a previous health care professional.

- (i) Tele-diagnosis is use of telecommunications technology for the identification of the nature of an illness or other problem by examination of symptoms.
- (j) Telehealth is the use of telecommunications technology to deliver health-related services and information that support patient care, administrative activities, and health education.
- (k) Telehealth Centre is the Centre for Excellence in Digital Health, Ministry of Health, Kingdom of Saudi Arabia.
- (l) Telehealth services includes tele-screening, tele-triage, tele-consultation, tele-diagnosis, tele-assistance, tele-treatment, and tele-monitoring
- (m) Tele-monitoring means the remote medical monitoring of a patient based on the medical and health data collected by a patient or a health care professional or a device.
- (n) Tele-screening is the use of telecommunications technology to conduct tests or examinations to discover illness or injury in a patient.
- (o) Tele-treatment is the use of telecommunications technology to cure a person of an illness or injury.
- (p) Tele-triage is the use of telecommunication technology for the assignment of degrees of urgency to wounds and illnesses to decide the order of treatment of a large number of patients or casualties.

2. Objective

- (1) The object of these regulations shall be to set the standards for all telehealth services and to monitor compliance with the standards by health care facilities and health care professionals within the Kingdom of Saudi Arabia.

3. Scope and Applicability

- (1) These regulations shall be applicable to all health care facilities and health care professionals associated with health care facilities, licensed by Ministry of Health to provide telehealth services.
- (2) These regulations shall be in force until 31st December 2021.

4. Practice of Telehealth Services

- (1) Telehealth services shall be practised only by health care facilities that are licensed by the Ministry of Health.
- (2) All health care facilities should have telehealth services for rendering care.
- (3) The health care facilities should comply with all the laws and regulations issued by Ministry of Health from time to time.

(4) An entity providing telehealth services which is not licensed as a health care facility in the Kingdom of Saudi Arabia shall obtain a licence to be allowed to practice telehealth from the Telehealth Centre.

(5) All legal requirements applied to a health care facility shall be applied to an entity providing telehealth services.

5. Requirements for providing medical care in Tele-health

(1) A health care facility involved in telehealth services shall comply with the Ministry of Health requirements for licensure and other requirements necessary for its operation, while licenses will be granted as per the below:

a) Public sector: Pre-approvals shall be obtained from Digital Health Centre of Excellence prior activating Tele-health services

b) Private sector: Licenses are granted before Tele-health services activation through the Licensing Department of the Ministry of Health in line with the requirements of Digital Health Center of Excellence.

(2) A health care facility shall employ the minimum number of physicians for the provision of telehealth services as per the Ministry of Health policy for licensing health facilities.

(3) A health care facility shall install equipment, devices and technologies approved by Ministry of Health needed for the delivery of telehealth services including software and peripheral devices.

(4) A health care facility shall have a written contract with another health care facility where the telehealth service provision entails two or more entities.

(5) The contract should detail out the roles and responsibilities of each party and should be in alignment with the law and regulations of the Kingdom of Saudi Arabia.

(6) The health care facility shall maintain a record of all physicians and other health care professionals engaged in telehealth services.

(7) The health care facility shall be responsible to ensure that the partnering health facility, which is not subject to the jurisdiction of the Kingdom of Saudi Arabia, is made aware of all the applicable laws and regulations for telehealth services and assure compliance across both jurisdictions.

(8) The health care facility shall have in place policies relating to telehealth service description with scope of services available, patient identification, selection and risk assessment and patient consent.

6. Requirements for health care professionals

(1) Telehealth services related to diagnosis and treatment shall be led by a physician.

(2) Telehealth services may be practiced by all types of health care professionals for which they are

credentialed and privileged.

(3) All legal requirements applicable to health care professionals practising within the jurisdiction of the Kingdom of Saudi Arabia shall be applicable to the practice of telehealth.

(4) Health care professionals shall be allowed to practice telehealth services across all types of health care providers in the Kingdom of Saudi Arabia.

(5) Health care professionals practicing telehealth services may be remunerated for the practice.

7. Credentialing and Privileging

(1) The practice of telehealth shall be restricted to the healthcare professionals who are credentialed to practice within the jurisdiction of the Kingdom of Saudi Arabia.

(2) The licensed physicians, nurses and allied health professionals must be privileged to provide telehealth services as per the Ministry of Health requirements for Clinical Privileging.

(3) Telehealth services must comply with laws and regulations of KSA and work within the scope of their license, speciality and granted privileges.

(4) Physicians providing telehealth services shall comply with the professional licensure requirements.

(5) Nurses and other health care professionals may provide telehealth services related to diagnosis and treatment under the direction and clinical supervision of the treating physician.

(6) A healthcare facility licensed by the Ministry of Health for providing telehealth services shall privilege its staff to provide telehealth services by speciality and document it in the staff's records.

(7) The health care facility providing telehealth services shall be accredited from an internationally recognised accreditation organisation for telehealth services within 18 months or such extended time period as may be prescribed by the Telehealth Centre, from the date of commencement of telehealth services.

8. Insurance Coverage

(1) Provision shall be made for the health insurance coverage to include telehealth services.

(2) Private health insurance shall provide coverage of telehealth services with at least a parity of public coverage and funding in telemedicine services.

9. Liability and Malpractice

(1) In a telehealth service involving two or more healthcare professionals, each healthcare professional shall be responsible based on their individual contribution.

(2) Liability shall be decided on a case-to-case basis after due investigation.

(3) The health care facility shall ensure malpractice insurance is in place throughout the duration of the telehealth service.

(4) Telehealth services rendered by a healthcare professional shall be covered by malpractice insurance.

10. Telehealth Centre

(1) The Telehealth Centre shall support, monitor, and evaluate the implementation and development of telehealth services in the Kingdom of Saudi Arabia.

(2) The Telehealth Centre shall set the standard for telehealth services, monitoring compliance with the standards by health care facilities and professionals and conducting evaluations relating to telehealth services.

(3) Health care facilities and professionals practising telehealth in the Kingdom of Saudi Arabia shall declare themselves to Telehealth Centre through an online form and update it annually.

(4) Health care facilities shall provide an annual report to the Telehealth Centre on the status of implementation and impact of telehealth services in the Kingdom of Saudi Arabia.

(5) Health care facilities shall use medical devices in telehealth services approved by the Saudi Food and Drug Authority. Devices not regulated by the Saudi Food and Drug Authority shall be approved by the Telehealth Centre on a case-to-case basis after due investigation.

(6) If two or more healthcare facilities provide a collaborated telehealth service, they shall enter into a written agreement and a copy of the same shall be submitted to the Telehealth Centre.

11. Health information and Identity

(1) The health care facility shall provide for secure and private workspace to safeguard patient privacy which includes privacy of personal information, privacy of personal communications and privacy of consulting space.

(2) Telehealth services shall be compliant with the health information exchange policy as applicable within the Kingdom of Saudi Arabia, including all relevant data security, privacy requirements and interoperability frameworks.

(3) Health care facility and professionals shall have sufficient evidence to identify the patient before and during the telehealth service.

(4) Healthcare professionals shall have access to all relevant patient health and medical information relevant to the practice of telehealth services.

12. Patient rights and Dispute Resolution

(1) The health care facility offering telehealth services shall obtain informed consent before the commencement of the telehealth service from the patient and the same shall be signed by patient

and available online for verification.

- (2) Informed consent signed shall be valid for telehealth services rendered by the health care facility.
- (3) The standard informed consent form shall include telehealth services.
- (4) The health care facility shall make a provision for patients to receive relevant education on telehealth services.
- (5) Patients shall be given the right to refuse or cancel any participation in telehealth services at any time without the need to provide any reason.
- (6) The health care facility shall make a provision for patients to make a complaint about a telehealth service which shall be shared with the Telehealth Centre at regular intervals.
- (7) Any user of telehealth services can register a complaint using the provisions provided by the health care facility.
- (8) The health care facility shall file quarterly reports to the Telehealth Centre with details about the number of complaints filed, the types of complaints, the process by which the complaints were redressed and the outcome of the complaints.
- (9) The Telehealth Centre may directly receive complaints from the users of telehealth services filed in the prescribed manner.

13. Permitted Services

- (1) Permitted telehealth services include scheduling appointments, medical assessment, medical advice, consultation, treatment, referral, peer-to-peer sessions, therapy, laboratory testing, diagnostics, surgery, monitoring chronic conditions, counselling, prescription of medicines, dispensing of medicines and exchange of medical reports.
- (2) The list of permitted services shall be revised by the Telehealth Centre from time to time.

