

# The Regulation and Licensing of Telemedicine in Saudi Arabia

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The means of diagnosing illness has developed over the last five years and patients are no longer solely examined by a healthcare practitioner ('HCP') in an examination room with consultations to other HCPs where necessary. There are now a number of resources available to HCPs in providing a diagnosis to patients and the use of telemedicine is popular within the region.

Until recently, telemedicine was a tolerated practice within the Kingdom of Saudi Arabia ('KSA') with no licensing availability or possibility for investment domestically or through foreign investment. As telemedicine took off worldwide, KSA was in serious danger of being left behind, as the potential for development could not be realised at the time. Everything quickly changed and a telemedicine licensing regime was introduced in December 2018 and the Telemedicine Regulations were published in June 2019. Finally, KSA is able to take advantage of all the benefits that telemedicine can offer with in-country investment being a viable option for foreign investors.

## Telemedicine Regulations

The Telemedicine Regulations ('Regulations') have been published and set out the specifications and requirements for telemedicine practice within KSA. The Regulations state that telemedicine is available for

screening, triage, consultation, diagnostics, obtaining a medical opinion from an HCP, treatment support, and the monitoring of medical conditions.

The Regulations define telemedicine as a remote medical practice using information and communication technology, which should be utilised either as an interaction between a patient and an HCP or between two or more HCPs. The interaction shall take place between two different sites and may involve robots or artificial intelligence.

Teleconsultations can either be between a patient and an HCP or between two or more HCPs and must involve a video consultation (teleconsultations cannot be solely audio) but need not be synchronous.

Telemedicine may be practised by any KSA accredited HCP within either the public or private sector. Telemedicine undertaken by an HCP outside the jurisdiction will be undertaken under the supervision of a KSA based HCP. The Ministry of Health ('MOH') now provides a telemedicine facility for its citizens. All legal requirements and protocols that are applied to an HCP in physical practice in KSA apply equally to the practice of telemedicine.

Telemedicine services can be chargeable and HCPs may be remunerated for the services and consultations they provide. Furthermore, private healthcare insurers must provide coverage within their insurance provision and all compulsory cover provided for within the Co-operative Health Insurance Law must be offered.

The Regulations provide that a government agency shall be created to regulate and monitor telemedicine and shall be named the Saudi Telemedicine Unit of Excellence, which will operate within the National Health Information Centre of the Saudi Health Council.

It is a provision of the Regulations that all HCPs must be trained in telemedicine before practising telemedicine and such training must be accredited by the Saudi Commission for Health Specialties. The training programme shall include content on telemedicine practice and regulations, the application of telemedicine to the HCP's speciality, and the use of telemedicine solutions, where appropriate.

An entity providing telemedicine services that is not licensed as a healthcare facility in the KSA is capable of obtaining a licence to practise telemedicine, and we refer you to the licensing regime below. All legal requirements and protocols applied to healthcare facilities in KSA apply equally to entities providing telemedicine services, including obtaining accreditation from the Saudi Central Board for Accreditation of Healthcare Institutions.

The practice of telemedicine must be compliant with the health information exchange policy in KSA, including all appropriate data security and patient privacy requirements, and furthermore, must be compliant with interoperability frameworks.

In practising telemedicine, HCPs should have sufficient evidence to identify the patient who is seeking a consultation and should have access to all relevant patient health and medical information of the patient where available. All patients seeking a teleconsultation must sign a consent form in relation to the consultation (preferably prior to undertaking a teleconsultation).

An HCP practising telemedicine may prescribe online prescriptions or undertake medical investigations. Both actions should abide by all relevant regulations and protocols that apply to such actions in KSA.

All telemedicine activities should be formally recorded within the patient's medical records and should include information relating to the telemedicine service provider, the location of the consultation, the activities undertaken, the date and time of the consultation, and details of any prescriptions and/or medical investigation provided together with all observations made during the consultation.

# Telemedicine Licensing Regime

MOH has published an annex to the Private Healthcare Institutions Law (Annex 24), which provides for a licensing regime for Telemedicine and Remote Care Centres ('Telemedicine Centres') in KSA.

The MOH has also published a Healthcare Investor Licensing Guide ('Guide') that defines a Telemedicine Centres as:

*“private health facilities, designed to use a range of modern electronic technologies, such as multimedia, e-mail and smart applications, by health facilities or practitioners, so as to enable safe and direct communication between the patients and health practitioners to assess their medical conditions and provide necessary treatment thereto.”*

Telemedicine Centres are classified as Support Health Services Centres ('SHSC') and all SHSC must have a Managing Director who is a Saudi national responsible for supervision of the Telemedicine Centre and a technical supervisor who is a telemedicine specialist.

All Telemedicine Centres must have a specialised physician to provide consultations (who need not be a Saudi national).

All applications for a telemedicine licence should be submitted to the Directorate of Health Affairs with supporting documentation and pre-approval from the MOH. An applicant must have a valid commercial registration certificate and further must obtain Ministry of Municipal and Rural Affairs ('MOMRA') approval for the proposed location of the Telemedicine Centre, which must be followed by an application for approval through the SEHA platform and finally a permit from MOMRA. Approval must be obtained for the Telemedicine Centre's medical personnel from the Directorate of Health Affairs and the Ministry of Labour and Social Development electronically. Finally, a telemedicine licence must be obtained before the Telemedicine Centre can operate.

## Telemedicine Centres

All Telemedicine Centres will need to provide either a website or mobile application that provides comprehensive and detailed information about the services they are providing. They must also have a separate administrative head office and a separate medical facility ('Medical Facility') where remote medical examinations can be conducted by a physician. The Medical Facility need not be managed, operated or owned by the Telemedicine Centre but can be made available through a third party via a commercial arrangement. The Medical Facility must have appropriate medical equipment and the Telemedicine Centre will need an electronic health record system to record all data collected. Finally, the Telemedicine Centre will need to provide adequate training for its employees in accordance with the Regulations.

Telemedicine Centres do not need to be owned by medically qualified investors nor does the investor have to be a Saudi national or Saudi owned entity; therefore, telemedicine is open to foreign investment in KSA. Furthermore, telemedicine services can be provided to KSA citizens from outside the country (under the appropriate supervision of a Telemedicine Centre or healthcare institution within KSA). Telemedicine Centres allow for the collaboration between medical institutions to share knowledge and experience. It enables healthcare professionals within the country to have access to and assistance from experts outside the Kingdom, which will benefit patients and will enable Saudi based medical practitioners to develop expertise in their chosen field. Telemedicine practice is a growth area, which can only go from strength to strength and which offers excellent investment opportunities for domestic and foreign investors alike.

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