

# DOH STANDARD ON TELE-MEDICINE September 2020

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This document should be read in conjunction with Federal laws and DOH regulations including:

- Federal laws on Medical Liability and the Practice of Human Medicine.
- Annex to Cabinet Resolution no. 40 for 2019 Governing Tele-health Services.
- Legal requirement for patient consent and confidentiality of patient information.
- DOH Provider Manual.
- DOH Professional Manual.
- DOH Regulator Manual.
- DOH Insurance Manual.
- Abu Dhabi Healthcare Information and Cyber Security Standard.
- DOH Data Management Policy and DOH Data Standards.
- DOH Policy on Cultural Sensitivity.
- DOH Policy on Health Information Exchange.
- DOH Policy on Digital Health.
- DOH Policy on Artificial Intelligence in the Healthcare Sector of the Emirate of Abu Dhabi.
- DOH Standard on the Internet of Medical Things Security.
- DOH Standard for Patient Healthcare Data Privacy.
- DOH policies and standards on medical devices and others.



#### 1. Purpose

To define the minimum requirements for the provision of tele-medicine services by DOH licensed providers to ensure safe and quality services and covering:

- 1.1. Tele-diagnosis.
- 1.2. Tele-counseling.
- 1.3. Tele-medical interventions.
- 1.4. Tele—consultation.
- 1.5. Tele-prescription.
- 1.6. Tele-monitoring.

#### 2. Scope

This standard applies to:

- 2.1. Healthcare facilities licensed or approved by DOH to provide tele-medicine services.
- 2.2. Eligible patients that meet the DOH applicable criteria.
- 2.3. Diseases and conditions that are suitable to be treated and managed through tele-medicine.

#### 3. Definitions and Abbreviations

#### 3.1. Data/Biodata:

As used in this standard, is data related to the patient's underlying medical condition including associated images, reports, laboratory investigations and vital signs. It can also include data on the date and time of the tele-medicine encounter and history of encounters.

#### 3.2. Distant facility/professional:

Remotely located and licensed healthcare facility/professional from which tele-diagnostic or tele-counseling services are being sought or provided to. The remote healthcare facility/professional must be licensed by DOH or by the health regulator in the region in which it is located and must agree to provide the diagnostic or counseling services requested by the originating healthcare facility/professional by means of telecommunication media.

#### 3.3. Electronic medical record:

Means a repository of patient medical data in digital form, stored and exchanged securely, and accessible by multiple authorized users.

#### 3.4. Invasive clinical intervention:

Of or relating to a medical procedure in which a part of the body is entered, as by puncture or incision to gain access to the target of surgery, endoscopy, or such interventions.

#### 3.5. Local facility/professional:

The DOH-licensed healthcare facility/professional located in the Emirate of Abu Dhabi from which or to which a request for tele-diagnostic or tele-counseling is raised.

#### 3.6. Originating facility/professional:

The licensed healthcare facility requesting the tele-diagnostic or tele-counseling service.

#### 3.7. **Patients**:

All eligible patients determined by the treating physician for which tele-monitoring is clinically indicated.

#### 3.8. **Point of Care Testing (POCT)**:

Refers to any testing conducted outside the premises of a purposefully DOH licensed clinical laboratory facility or environment, but in either a DOH licensed healthcare facility, generally nearer



to, or at the site of, the patient or a non-healthcare facility environment, such as the patient's home; (Refer to the Standard on POCT).

#### 3.9. Tele-counseling provider:

A healthcare facility licensed by DOH to provide tele-counseling services and/or healthcare professionals employed by a DOH licensed facility (tele-counseling) authorized/privileged by their employing facility to provide tele-counseling healthcare services. This can include general practitioners, family doctors and other specialists as long as they are privileged by their facility to provide that clinical service. The patient may be located at their home, or another location.

#### 3.10. **Tele-counseling**:

As per the Annex to the Cabinet Resolution No. 40, 2019 Governing Tele-health services, it is the use of Information and Communication Technology by physicians in geographically separate healthcare facilities to remotely provide counsel/advice on the management of a health condition as an adjunct to the delivery of healthcare services including for patients whose primary treating physicians may be located outside the country.

#### 3.11. Tele-consultation

In line with the Annex to the Cabinet Resolution No. 40, 2019 Governing Tele-health services, it is the use of Information and Communication Technology by a DOH licensed tele-medicine provider and a patient in a geographically different location to remotely provide consultation on the management of a health condition.

#### 3.12. Tele-consultation provider:

- 3.12.1. A healthcare facility licensed by DOH to provide tele-consultation services and / or
- 3.12.2. Physicians employed by a DOH licensed facility authorized or privileged by their employing facility to provide tele-consultation services and/or
- 3.12.3. Healthcare professionals, other than physicians, who are dealing with patient or practicing any healthcare activity that is part of the patient's treatment, provided they are accountable in the normal course of practicing, and who are privileged by the facility to provide tele-consultation services.

#### 3.13. **Tele-diagnosis:**

As per the Annex to the Cabinet Resolution No. 40, 2019 Governing Tele-health services, it is the use of Information and Communication Technology between providers (i.e. facilities) in geographically separate locations to transmit patients' physical examination records, including x-rays and records of images and videos, and medical reports for the purpose of diagnosis of patients' conditions.

#### 3.14. Tele-diagnosis provider:

Is a licensed healthcare facility in the UAE that is contracted by a DOH-licensed facility to provide it with remote diagnostic services.

#### 3.15. **Tele-medicine**:

Includes remote-based physician-to-patient consultation, physician-to-physician counseling, prescription, diagnostic, medical intervention and health monitoring services enabled by a range of telecommunications media such as, telephone, internet-based video, email and/or similar electronic-based communications. Telemedicine encounters, other than tele-medical interventions, are of two types: synchronous or asynchronous. Synchronous tele-medicine occurs when the provider is not physically in the same place as the recipient of the service, but they are interacting in real-time. In asynchronous tele-medicine encounters, the provider and recipient actions are separated in both space and time.

#### 3.16. **Tele-medicine provider:**



A healthcare facility licensed by DOH to provide tele-medicine services and/or healthcare professional employed by a DOH licensed facility /privileged by their employing facility to provide tele-medicine healthcare services. This can include general practitioners, family doctors and other specialists as long as they are privileged by their facility to do so. The patient may be located at their home, or another location.

#### 3.17. **Tele-monitoring**:

As per the Annex to the Cabinet Resolution No. 40, 2019 Governing Tele-health services, it is the use of Information and Communication Technology to remotely collect the patient's vital signs and other clinical indicators of health to monitor the patient's health condition.

#### 3.18. **Tele-monitoring equipment**:

Devices and supporting systems used to automatically transmit signals from remotely-located patients to a central station where abnormalities will trigger a response by healthcare professionals or those that support the monitoring of data quality, utilization management review and risk management.

#### 3.19. Tele-monitoring healthcare service providers:

A DOH licensed healthcare facility authorized by DOH to provide tele-monitoring services. Patients may be located at their home, or temporarily in another location.

#### 3.20. Tele-prescribing service:

As per the Annex to the Cabinet Resolution No. 40, 2019 Governing Tele-health services, it is prescribing of medication by a physician to a patient in a different geographic location using Information and Communication Technology and following an ICT-enabled remote examination of the patient by the physician or based on a diagnosis made based on patient physical examination.

#### 3.21. Tele-prescribing service provider:

A healthcare facility licensed by DOH to provide tele-prescribing services. Patients may be located at their home, or in another location.

#### 3.22. Tele- medical interventions:

As per the Annex to the Cabinet Resolution No. 40, 2019 Governing Tele-health services, it is the use of Information and Communication Technology for any remote medical intervention. For the purpose of this standard, this refers to medical procedures such as surgeries, treatments and diagnosis remotely conducted using robotic systems and wired and/or wireless communication networks.

- 3.23. **Treating physician**: A DOH licensed General practitioner, specialist or consultant who offers an opinion within his area of specialty and provides treatment to a patient for a specific condition.
- 3.24. **Wired network**: A network that uses cables to connect devices, such as laptop or desktop computers, to the Internet / another network.
- 3.25. **Wireless network**: A network that uses radio waves and allows devices to stay connected to the network but roam untethered to any wires.

#### 4. Licensing Requirements

- 4.1. A DOH license is required for the provision of tele-medicine services.
- 4.2. A facility may seek a license to provide tele-medicine services through:
  - 4.2.1. Application for a new facility license to provide tele-medicine services; or
  - 4.2.2. Application to add a tele-medicine service under an existing DOH licensed facility.
- 4.3. Approved facilities will be issued with a license specifying the particular tele-medicine service they will be providing.



- 4.4. Only those healthcare facility types defined below are eligible for consideration for either licensure (as a new facility application) or addition of a new service (for facility with existing DOH license) to provide:
  - 4.4.1. Tele-medical interventions:
    - 4.4.1.1. Hospitals.
    - 4.4.1.2. Medical Centers with Surgical Services.
    - 4.4.1.3. One-Day Surgical Centers.
  - 4.4.2. Tele-counseling:
    - 4.4.2.1. Hospitals.
    - 4.4.2.2. Medical centers.
    - 4.4.2.3. Clinics.
    - 4.4.2.4. Diagnostic centers.
    - 4.4.2.5. Rehabilitation centers.
    - 4.4.2.6. Mobile health units-Medical Clinics.
    - 4.4.2.7. Tele-medicine providers.
  - 4.4.3. Tele-consultation:
    - 4.4.3.1. Hospitals.
    - 4.4.3.2. Medical centers.
    - 4.4.3.3. Clinics.
    - 4.4.3.4. Rehabilitation centers.
    - 4.4.3.5. Mobile health units.
    - 4.4.3.6. Tele-medicine providers.
  - 4.4.4. Tele-prescription:
    - 4.4.4.1. Hospitals.
    - 4.4.4.2. Medical centers.
    - 4.4.4.3. Mobile health units-Medical and Dental.
    - 4.4.4.4. Tele-medicine providers.
  - 4.4.5. Tele-diagnostic services:
    - 4.4.5.1. Hospitals.
    - 4.4.5.2. Medical Centers.
    - 4.4.5.3. Medical Laboratories.
    - 4.4.5.4. Diagnostic Centers.
    - 4.4.5.5. Mobile health units.
  - 4.4.6. Tele-monitoring services:
    - 4.4.6.1. Hospitals.
    - 4.4.6.2. Centers.
    - 4.4.6.3. Provision of Health Services Home healthcare.
    - 4.4.6.4. Tele-medicine providers.
- 4.5. Professionals providing tele-medicine services do not require specific tele-medicine license. Only a DOH healthcare professional license is required and will be issued by DOH in accordance with the professionals licensing requirements.

#### 5. General Duties of Tele-medicine Providers

5.1. The legal and DOH regulations that apply to face-to-face healthcare also apply to tele-medical care.



- 5.2. In addition, tele-medicine services in the Emirate of Abu Dhabi are also governed by the specific terms and conditions attached to tele-medicine and to each branch of tele-medicine as per the Annex to the Cabinet Resolution No. 40, 2019 Governing Tele-health services (see Appendix 3).
- 5.3. DOH licensed tele-medicine service providers must also have the right physical infrastructure for the tele-medicine areas to preserve the privacy, access to and confidentiality of case details.
- 5.4. As per the Annex to the Cabinet Resolution No. 40, 2019 Governing Tele-health services, providers of tele-medicine services must demonstrate that the services will be performed by healthcare professionals with the appropriate skills, training and knowledge in tele-medicine technologies and tools when applying for the license.
- 5.5. Providers of tele-medicine services must have in place data management systems and protocols that maintain the confidentiality of gathered personal/patient information and that access to, use, sharing and transmission and reporting of such data complies with relevant DOH regulations.
- 5.6. Where applicable, especially in the case of tele-diagnostic, tele-counseling and tele-consultation, have policies and procedures in place for at least the following elements:
  - 5.6.1. Collaborations, affiliations, agreements and/or contracts with other healthcare providers in the healthcare system to support delivery and continuity of care.
  - 5.6.2. Managing image sharing and transmission.
- 5.7. Ensure the availability of the right ICT infrastructure and supportive environment for the telemedicine service provided including:
  - 5.7.1. Availability of the requisite range of equipment and that equipment choice, maintenance and servicing support quality and timely or real-time, as appropriate, transmission of relevant information and/or data and/or medical imaging results.
  - 5.7.2. Information and communication technology (ICT) Policies, procedures and systems to assure the safe, effective and secure transmission of health information and its confidentiality.
  - 5.7.3. Regular monitoring and assessment of the ICT infrastructure and supportive environment to assure their effectiveness.
  - 5.7.4. ICT policies, procedures and systems that meet the Abu Dhabi Digital Authority (ADDA) and DOH technical and security regulatory requirements and that afford a high degree of interoperability.
  - 5.7.5. Protocols for network security, confidentiality, privacy and connectivity and protection of confidentiality and privacy of recorded images with regular assessments to ensure the effectiveness of all systems.
  - 5.7.6. Systems in place to ensure sufficient availability of the network for critical connectivity.
  - 5.7.7. Standard procedures for any emergency event or technical failures for communication equipment, devices and IT systems to assure the security and protection of the patient health records.
- 5.8. Comply with:
  - 5.8.1. All relevant laws, policies and regulations.
  - 5.8.2. DOH requests to inspect and audit records and cooperate with DOH authorized auditors, as required for inspections and audits by DOH.
  - 5.8.3. The data submission and reporting requirements specified in the Data Management Policy Chapter, Healthcare Regulator Manual.
  - 5.8.4. Request of the authorized insurance company to audit the electronic medical records/related information, such as billing.



- 5.9. Document, report and update DOH on activities, as requested, in support of achieving the objectives of this Standard.
- 5.10. When requested make patient data available to DOH in a format compliant with DOH specifications and audit purposes.

#### 6. General Governance and Quality-Related Requirements:

As per the Annex to the Cabinet Resolution No. 40, 2019 Governing Tele-health services, providers of tele-medicine services must have a clinical governance framework in place to ensure the quality and safety of their services. The clinical governance framework is to include but not be limited to:

- 6.1. Quality & Safety Assurance systems:
  - 6.1.1. Evidence-based guidelines to describe the purposes of the facility's tele-medicine services, including scope and specifications.
  - 6.1.2. Quality and safety monitoring and recording system or process.
  - 6.1.3. Risk control and management processes.
- 6.2. Staff training guidelines on the secure use of supportive technologies.
- 6.3. Governance and management protocols and Standard Operating Procedures with clearly defined and documented roles, responsibilities and accountabilities for management oversight and operational aspects (medical care and technical IT systems) including:
  - 6.3.1. Quality and security of data for tele-medicine services.
  - 6.3.2. Appropriate use of the tele-medicine services by the staff involved in the tele-medicine service.
  - 6.3.3. Downloading and uploading patient data.
  - 6.3.4. Recording and storing of patient's data.
- 6.4. Upholding of patient's rights and patient's consent:
  - 6.4.1. Patient's verbal or electronic consent for assessment and receipt of treatment and/or surgery, the creation of a medical record, access to patient's information and for insurance purposes.
    - 6.4.1.1. Verbal consent is to be recorded and also documented on the patient's records.
    - 6.4.1.2. Electronic consent can be obtained via technology-enabled communication media.
  - 6.4.2. Provision of transparent and clear information on the service to be provided including risks and the identity of the healthcare professionals providing the service, their qualifications, experience and training.

#### 7. Enforcement and Sanctions

DOH may impose sanctions in relation to any breach of requirements under this standard in accordance with the Complaints, Investigations, Regulatory Action and Sanctions Chapter, Healthcare Regulator Manual.



#### 8. Tele-Diagnostic Services-Additional Duties and Requirements:

#### 8.1. Eligibility Criteria/Case Mix:

Tele-diagnosis services may be used in support of patient cases where:

- 8.1.1. Capacity or remoteness issues hinder access to services.
- 8.1.2. The facility has limited capacity and/or capability in the concerned specialty area.
- 8.1.3. Complex cases that requires input and support from other specialists and/or a multidisciplinary team.

#### 8.2. Licensing, Consent and Data Security:

Refer to the Annex to the Cabinet Resolution No. 40, 2019 Governing Tele-health services for licensing, consent and security of data storage and data exchange requirements.

#### 8.3. Specific Duties of Healthcare Facilities requesting Tele-Diagnostic Services:

- 8.3.1. Primary responsibility for clinical and medical healthcare decision resides with the originating facility that is seeking tele-diagnostic services. It remains responsible to provide appropriate healthcare to the patient.
- 8.3.2. Written and evidence of adherence to quality assurance and improvement policies and procedures that govern the use of tele-diagnosis.
- 8.3.3. Policies and procedures in place to also include the following elements:
  - 8.3.3.1. Managing patient data sharing and transmission (including image and video or audio recording if available).
  - 8.3.3.2. Management of patient records including physical and electronic patient records.
  - 8.3.3.3. Network security, confidentiality, privacy and connectivity and protection of confidentiality and privacy of recorded images.

#### 8.4. Specific Technical & ICT-Related Requirements

Healthcare facilities utilizing tele-diagnosis services must ensure that:

- 8.4.1. They have the appropriate equipment & devices to support transmission and receipt of all diagnostic and assessment needs of the patients, that the equipment and devices are in good functioning order at the time of tele-diagnosis, such as when imaging and monitoring data are being exchanged, and that they are appropriately maintained and serviced in accordance with the manufacturer's specifications.
- 8.4.2. The equipment and devices are compatible with that of the distant site providing telediagnosis services.
- 8.4.3. Patients test results and health data when used to support tele-diagnosis services are of high quality, clarity, and legibility including all images.

#### 8.5. Specific Tele-Diagnostic Contractual Requirements:

DOH licensed healthcare providers seeking tele-diagnosis services are legally required to have a contractual agreement with tele-diagnosis service providers (refer to the Annex to the Cabinet Resolution No. 40, 2019 Governing Tele-health services).

8.5.1. Such contracts are required to:



- 8.5.1.1. Satisfy compliance, alignment and consistency as applicable to each partners' services with the requirements of this Standard, the scope, nature and application of the tele-diagnosis services.
- 8.5.1.2. Assign a designated facility management team/staff responsible for approving and managing contractual/partnership agreements in accordance with good governance practices.
- 8.5.1.3. Ensure that the DOH licensed originating facility maintains responsibility for the patient's assessment, test findings and diagnosis, care and management, and the continuity of patient care.
- 8.5.1.4. Ensure that where a tele-diagnosis partner is located outside of the Emirate of Abu Dhabi, that their contractual relationship with that partner requires the partner to comply with the requirements of the local health authority and Abu Dhabi Emirate specific regulations and that services are provided to specified performance indicators to assure the safety and quality of care.
- 8.5.1.5. Ensure that all DOH and Abu Dhabi Emirate applicable administrative, clinical and technical requirements are appropriately addressed in partnership arrangements.

#### 8.6. Payment Mechanism

- 3.6.1. Distant provider will bill the originating provider based on the agreement between them.
- 8.6.2. Payment mechanism for tele-diagnostic services shall be in accordance with Standard Provider Contract, DOH Mandatory Tariff and associated Claims and Adjudication Rules; all documents are available from <a href="https://www.doh.gov.ae/en/Shafafiya/dictionary">https://www.doh.gov.ae/en/Shafafiya/dictionary</a>.



#### 9. Tele-Counseling Services-Additional Duties and Requirements:

#### 9.1. Eligibility Criteria/Case Mix:

Tele-counseling services may be used in support of patient cases where:

- 9.1.1. Capacity or remoteness issues hinder patient access to services (e.g. Lack of clinical service line or specialty area or underserved areas); a requesting healthcare professional must only practice within their DOH license, job duties and privileges granted by the employing facility.
- 9.1.2. The treating physician has limited skills in the concerned specialty area, but his/her practice remains within their DOH license and privileges granted by the employing facility.
- 9.1.3. Complex case that requires input and support from other specialists and/or a multidisciplinary team.

#### 9.2. Specific Duties of Healthcare Facilities and Professionals

- 9.2.1. Must assure the integrity and credibility of and accountability for tele-counseling services;
- 9.2.2. Must protect the privacy concerns of the patient and the confidentiality and security of their medical information and records at the site of patient counseling (originating facility), and during transmission to another healthcare professional/provider (distant facility).
- 9.2.3. Sharing of healthcare data outside UAE needs authorization from DOH, as per UAE Federal Law No. 2, 2019.
- 9.2.4. The originating DOH licensed healthcare facility or professional seeking tele-counseling services is responsible for ensuring that the facility or professional it seeks it from is licensed by DOH, if located in Abu Dhabi, or by the respective regulatory authority in the UAE or the country specific regulator, if located outside of UAE.

#### 9.3. Specific Tele-counseling Governance and Quality-related Requirements:

Facilities /professionals utilizing tele-counseling services must have:

- 9.3.1. Written and evidence of adherence to quality assurance and improvement policies and procedures that govern the use of tele-counseling.
- 9.3.2. Policies and procedures covering the following elements:
  - 9.3.2.1. Management of the patient's data (including image and video or audio recording if available) sharing and transmission.
  - 9.3.2.2. Management of patient records including physical and electronic patient records; including recording of video/web/phone consultation.
  - 9.3.2.3. Network security, confidentiality, privacy and connectivity and protection of confidentiality and privacy of recorded images.
- 9.3.3. Primary responsibility for clinical and medical healthcare decision resides with the originating facility. It remains responsible to provide appropriate healthcare to the patient.

#### 9.4. Specific Staffing and Training Requirements:

The healthcare facility utilizing tele-counseling services must ensure that:

9.4.1. It assess its staff training needs and provides training in tele-medicine technologies, where identified as necessary.



9.4.2. The facility must maintain an up-to-date record of its staff tele-medicine training, whenever conducted.

#### 9.5. Specific Technical & ICT-Related Requirements

- 9.5.1. Healthcare facilities utilizing tele-counseling services must ensure that they have the appropriate equipment & devices, including video and examination equipment where required, to support transmission and receipt of all diagnostic and assessment needs of the patients.
- 9.5.2. They must ensure that the equipment and devices are in good functioning order at the time of tele-counseling, such as when imaging and monitoring data are being exchanged.
- 9.5.3. They are appropriately maintained and serviced in accordance with the manufacturer's specifications.
- 9.5.4. They are compatible with that of the distant site providing tele-counseling services.
- 9.5.5. Patients test results and health data when used to support tele-counseling services are of high quality, clarity, and legibility including all images.

#### 9.6. Specific Tele-counseling Collaborative Partnerships-Related Requirements:

DOH licensed healthcare facilities utilizing tele-counseling services are expected to have in place written arrangements (i.e. agreements, memoranda of understanding and/or contracts) with tele-counseling service providers. In case of International Patient Care patients sponsored by DOH, provision of tele-counseling shall be provided as per the requirements of DOH.

- 9.6.1. The contracts/partnerships must be with healthcare entities that are able to demonstrate compliance with their country specific regulatory body, including the provision of medical liability insurance.
- 9.6.2. Such contracts are required to:
  - 9.6.2.1. Satisfy compliance, alignment and consistency as applicable to each partners' services with the requirements of this Standard, the scope, nature and application of the tele-counseling services.
  - 9.6.2.2. Assign a designated facility management team/staff responsible for approving and managing contractual/partnership agreements in accordance with good governance practices.
  - 9.6.2.3. Ensure that the DOH licensed originating facility /professional maintains responsibility for the patient's assessment, test findings and diagnosis, care and management, and the continuity of patient care; they are also accountable and liable for medical and clinical care decisions relating to the treated patient.
  - 9.6.2.4. Ensure that where a tele-counseling partner is located outside of the Emirate of Abu Dhabi, that their contractual relationship with that partner requires the partner to comply with the relevant country and Abu Dhabi Emirate specific regulations and that services are provided to specified performance indicators to assure the safety and quality of care.
  - 9.6.2.5. Ensure that all DOH and Abu Dhabi Emirate applicable administrative, clinical and technical requirements are appropriately addressed in the partnership arrangements.
- 9.6.3. When establishing collaborative partnerships, a DOH licensed facility must comply with applicable legal and regulatory requirements in the Emirate of Abu Dhabi.



#### 9.7. Payment Mechanism

Payment mechanism for tele-counseling services shall be in accordance with Standard Provider Contract, DOH Mandatory Tariff and associated Claims and Adjudication Rules; all documents are available from <a href="https://www.doh.gov.ae/en/Shafafiya/dictionary.">https://www.doh.gov.ae/en/Shafafiya/dictionary.</a>



#### 10. Tele-Medical Interventions -Additional Duties and Requirements:

#### 10.1. Scope:

- 10.1.1. Healthcare facilities licensed by DOH to provide tele-medical interventions.
- 10.1.2. Healthcare professionals employed in tele-medicine facilities licensed to provide tele-medical interventions.
- 10.1.3. All devices and supporting systems used for the purpose of tele-medical interventions.

#### 10.2. Eligibility Criteria:

Tele-medical interventions may be used for patients deemed eligible for these services by their treating physician or healthcare provider to achieve better outcomes including lesser blood loss, lesser post-operative pain, shorter hospital stays and quicker resumption of daily activities.

#### 10.3. Specific Duties of Tele-medical intervention providers:

In addition to the general duties of tele-medicine providers, providers of tele-medical intervention services have additional service-specific duties and requirements:

- 10.3.1. Primary responsibility towards the patient resides with the healthcare professional & facility where the medical intervention on the patient is taking place. They remain responsible to provide appropriate healthcare to the patient.
- 10.3.2. Ensure that the physician performing the tele-medical intervention is licensed by DOH, if located in Abu Dhabi, or by the respective regulatory authority in the UAE or the country specific regulator, if located outside of UAE.
- 10.3.3. Ensure that there is a licensed health professional next to the patient at all times ready to intervene in the event of failure in the tele robotic system, including handling the robot on the intervention site.
- 10.3.4. Ensure that the physical infrastructure for the tele-medical intervention service areas complies with the DOH Guidelines for Health Facilities Design.
- 10.3.5. Ensure that any robotic system used for in the provision of the tele-medical intervention service is an assistive technology, thus not replacing the healthcare professional (i.e. autonomous) but is operated and controlled by the healthcare professional.
- 10.3.6. Ensure that each room used for tele-medical intervention service has the robotic equipment and instrumentation that is specific to the service to be provided in that room (i.e. Tele-robotic surgery and the particular type of tele-robotic surgery or Tele-robotic investigation and the particular type of tele-robotic investigation).
- 10.3.7. Must protect the privacy concerns of the patient and the confidentiality and security of their medical information and records at the tele-medical intervention site and during transmission to the operating physician.

#### 10.4. Specific Governance & Quality Related Requirements:

In addition to the general quality-related requirements specified above, tele-medical intervention providers have additional service specific governance and quality-related requirements.

- 10.4.1. A quality assurance and improvement structure that also includes:
  - 10.4.1.1.A Tele-robotics Program and leadership team with a minimum of a Director, a healthcare professional trained and experienced in tele-robotic services, robotics Clinical Head Nurse (if it is for tele-robotic surgeries), robotics coordinator and a lead for utilization and performance monitoring and metrics data collection.



- 10.4.1.2. Oversight function.
- 10.4.1.3. Privileging of staff.
- 10.4.1.4. Training of staff.
- 10.4.1.5. Monitoring of equipment and instrumentation.
- 10.4.1.6. Collection and monitoring of performance and quality related metrics.
- 10.4.1.7.Risk management plan to include delay in synchronization of commands and data exchange between the two sites involved in the tele-medical intervention.
- 10.4.1.8. Written and evidence of adherence to quality assurance and improvement policies and procedures that govern the use of tele-medical interventions.
- 10.4.1.9. Policies and procedures in place covering the following elements:
  - 10.4.1.9.1. Management of the patient's data sharing and transmission.
  - 10.4.1.9.2. Network security, confidentiality, privacy and connectivity and the protection of confidentiality and privacy of transmission.
- 10.4.1.10. Primary responsibility for clinical and medical healthcare decision resides with the facility where the patient is located. It remains responsible to provide appropriate healthcare to the patient.

#### 10.5. Specific Staffing and Training Requirements:

In addition to the general staffing and training-related requirements specified above, tele-medical intervention providers have additional service specific staffing and training requirements.

- 10.5.1. Privileging of staff to provide tele-medical intervention by specialty, and documenting it in the staff's records.
- 10.5.2. Having a policy on assessment of the staff's training needs and provision of training for all staff involved in the provision of tele-medical intervention services, prior to providing the service and on a refresher basis and having evidence of its implementation:
  - 10.5.2.1. The training program must be accredited by an internationally reputable entity that specializes in tele-medical intervention services.
  - 10.5.2.2. Provision of re-training on a regular basis and additionally when:
    - 10.5.2.2.1. Significant changes to the tele-medical intervention technologies used by the facility are introduced.
    - 10.5.2.2.2. New equipment are introduced.
    - 10.5.2.2.3. A competency issue with a trained staff member has been identified, which cannot be resolved in or by the healthcare facility.

#### 10.6. Specific Tele-Medical Intervention Collaborative Partnerships-Related Requirements:

- 10.6.1. DOH tele-medical licensed healthcare facilities utilizing tele-medical intervention services of others are expected to have in place written arrangements (i.e. agreements, memoranda of understanding and/or contracts) with the other licensed tele-medical intervention service providers.
- 10.6.2. In case of International Patient Care patients sponsored by DOH, tele-medical intervention services shall be provided as per the requirements of DOH.
- 10.6.3. The contracts/partnerships must be with healthcare entities that are able to demonstrate compliance with their Emirate or country's country specific regulatory body, including licensure and the provision of medical liability insurance.
- 10.6.4. The written agreements are expected to:



- 10.6.4.1. Satisfy compliance, alignment and consistency as applicable to each partners' services with the requirements of this Standard, the scope, nature and application of the tele-medical intervention services.
- 10.6.4.2. Assign a designated facility management team/staff responsible for approving and managing contractual/partnership agreements in accordance with good governance practices.
- 10.6.4.3. Ensure that the DOH licensed facility / professional maintains responsibility for the patient's assessment, test findings and diagnosis, care and management, and the continuity of patient care; they are also accountable and liable for medical and clinical care decisions relating to the treated patient.
- 10.6.4.4. Ensure that where a tele-medical intervention partner is located outside of the Emirate of Abu Dhabi, that their contractual relationship with that partner requires the partner to comply with the relevant country and Abu Dhabi Emirate specific regulations and that services are provided to specified performance indicators to assure the safety and quality of care.
- 10.6.4.5. Ensure that all DOH and Abu Dhabi Emirate applicable administrative, clinical and technical requirements are appropriately addressed in the partnership arrangements.

#### 10.7. Specific Technical and ICT Requirements

In addition to the general technical and ICT-related requirements specified above, tele-medical intervention service providers have additional service specific technical and ICT requirements:

- 10.7.1. The tele-medical intervention system is a clinically approved system as per the international certification and/or approval agencies recognized by the Ministry of Health and Prevention of the United Arab Emirates.
- 10.7.2. Same systems at the site of the surgeon controlling the system and the site of the robotic system.
- 10.7.3. Real-time or live two-way electronic communication utilizing suitable ICT tools (including video) to ensure low delay in communication between the surgeon controlling the system and the robotic system.
- 10.7.4. Appropriate systems in place to ensure sufficient availability of the network and bandwidth for critical connectivity and for medical video streaming;
- 10.7.5. Appropriate, functioning and well maintained and serviced equipment and devices, as per manufacturers' specifications, to support all tele-medical intervention-related needs of the patients.

#### 10.8. Payment Mechanism

10.8.1. Payment mechanism for tele-medical intervention must be in accordance with the Standard Provider Contract as applicable to the tele-medical interventions, DOH Mandatory Tariff and associated Claims and Adjudication Rules and the Coding Manual; all documents are available at the DOH website in Data Dictionary (https://www.doh.gov.ae/en/Shafafiya/dictionary).



#### 11. Tele-Consultation Services-Additional Duties & Requirements:

#### 11.1. Eligibility Criteria:

All patients seeking these services, in accordance with their health coverage.

- 11.2. Clinical services allowed to be provided via tele-consultation must be within the scope of the facility's license. Depending on the type of needed clinical service, they can be provided either by physicians who are privileged by the facility to provide tele-consultation services, or by other health professionals who are dealing with patient or practicing any healthcare activity that is part of the patient's treatment and are also privileged by the facility to provide these tele-consultation services. They shall be accountable to any practice that they execute towards the patient.
- 11.3. Services allowed to be provided via tele-consultation:
  - 11.3.1. Triage of patients; (patient prioritization and categorization according to medical and management needs, such as illness/injury, severity/complexity, prognosis and resource availability and referral to specialized care as indicated by case).
  - 11.3.2. Diagnosis.
  - 11.3.3. Video sighting of body symptoms.
  - 11.3.4. Tele-mental health services.
  - 11.3.5. Tele-monitoring (to comply with the articles under tele-monitoring) and the use of tele-monitoring devices for the home monitoring of patient health status and vitals (including for specified POCT).
  - 11.3.6. Tele-prescription. Prescribing of medications must be in accordance with existing federal laws, DOH regulations and applicable systems.
  - 11.3.7. Tele-pathology & Tele-radiology:
    - 11.3.7.1. Pathology requests can be sent to any healthcare provider as per the patient's convenience.
    - 11.3.7.2. Pathology request can be for point of care testing (POCT).
  - 11.3.8. Tele-Referral where applicable and relevant for the case.
  - 11.3.9. Follow up care and case management.
  - 11.3.10. Issuance of 1 day sick leave given that it is not an extension of an existing sick leave and is not issued retroactively.
  - 11.3.11. Recommendations for self-care.
  - 11.3.12. Home monitoring of patient health status and vitals including for specified POCT and the use of tele-monitoring devices.
  - 11.3.13. Any other tele-consultation medical services having met the requirements of this Standard as approved by DOH from time to time upon an application of a healthcare provider, or not. Examples may include provision of structured patient education, counseling and services associated with disease management programs, rehabilitation, speech, and physical therapy.

#### 11.4. Excluded Services:

- 11.4.1. Invasive clinical interventions.
- 11.4.2. Certificates such as fitness for work, disability assessment.
- 11.4.3. Adhoc telephone-consultations that may follow face-to-face consultations.
- 11.4.4. Patients identified as requiring invasive clinical intervention must be referred to the appropriate DOH licensed healthcare provider for face-to-face consultation and clinical examination.



#### 11.5. Specific Duties of Tele-consultation Providers:

In addition to the general duties of tele-medicine providers, tele-consultation services have additional service specific duties:

- 11.5.1. Comprehensive Electronic Medical Records and policies in place for the management of the patient's electronic medical records including recording of verbal consent and of video/web/phone consultation.
  - 11.5.1.1. Verbal consent should include re-confirmation of the patient's identity and should be recorded and also documented in the patient's electronic medical records.
  - 11.5.1.2. Recording of the entire video/web/phone consultation will be as judged as necessary by the physician.
- 11.5.2. Facilitate access to tele-medicine care through:
  - 11.5.2.1. Service availability timeframe that is in accordance with the identified needs and available workforce.
  - 11.5.2.2. A flexible patient appointment system that accommodates the availability of the patient and the service provider and the patient's needs and choice to access the service.
- 11.5.3. Have policies and procedures in place to assure the secure identification, authentication and authorization of patient, and where applicable their legal guardian, and to limit access to the patient records to authorized professionals providing tele-consultation healthcare services.
- 11.5.4. Register patients and verify patient personal identification information prior to offering the service.

#### 11.6. Specific Governance & Quality Related Requirements:

In addition to the Governance and Quality-related duties and requirements of tele-medicine providers, providers of tele-consultation services have additional service specific governance and quality related requirements.

- 11.6.1. Maintain the same level and/or improved quality of care compared to the face-to-face health services.
- 11.6.2. Must have a quality assurance and improvement framework that also includes:
  - 11.6.2.1.Quality committee or Quality Office for facilities staffed with more than 10 professionals.
  - 11.6.2.2. Collection of performance data, patient reported outcomes, patient satisfaction and service feedback.
- 11.6.3. Must have a patient referral system:
  - 11.6.3.1. Patients may be referred to other providers in cases such as but not limited to triage where the advice/decision of a physician/specialized physician is required, or for face-to-face consultation or other specific tele-health service.
  - 11.6.3.2. Patient referral, where if indicated must be:
    - 11.6.3.2.1. Timely especially for urgent cases assuring.
    - 11.6.3.2.2. Evidence-based best practice and informed by the physician/healthcare professional judgment in deciding when and where to refer, as per the patient's desire, service location and health insurance coverage;



- 11.6.3.3. There must be an open line of communication with the receiving physician/facility.
- 11.6.3.4. Referring physician/facility must hold responsibility for the decision of referral.

#### 11.7. Specific Care-Related Requirements:

- 11.7.1. Healthcare professionals providing tele-consultation services must follow industry good practice standards for services offered, including via telephone, internet, and video, among others.
- 11.7.2. Patient medical and health data must be used to support all tele-consultation encounters.
- 11.7.3. Physicians providing tele-consultation services have the continuous responsibility for making appropriate arrangements to follow the progress of the patients by monitoring the effectiveness and appropriateness of the recommended treatment, the need for further assessment and/or tele-referral and by informing other healthcare professionals involved in caring for the patient on their needs as appropriate and/or necessary.

#### 11.8. Specific Staffing and Training Requirements:

In addition to staffing and training requirements of tele-medicine providers, providers of tele-consultation services have additional service specific requirements.

- 11.8.1. Privileging of staff to provide tele-consultation services, and documenting it in the staff's records.
- 11.8.2. A internal policy on assessment of the facility's staff training needs and provision of training for all staff involved in the provision of tele-consultation services, prior to providing the service and on a refresher basis and having evidence of its implementation 11.8.2.1. The training program must be accredited (for tele-consultation) by an
  - internationally reputable entity that specializes in tele-medicine services.
- 11.8.3. Provision of re-training and/or updates annually, and additionally when:
  - 11.8.3.1. Significant changes to the tele-consultation technologies used by the facility are introduced.
  - 11.8.3.2. New equipment are introduced.
  - 11.8.3.3. A competency issue with a trained staff member has been identified, which cannot be resolved in or by the healthcare facility.
  - 11.8.3.4. A certified person, who, not having offered tele-health services for a period greater than six months, wishes to retain certification.

#### 11.9. Specific Technical and ICT Requirements

In addition to the ICT requirements of tele-medicine providers in general, providers of teleconsultation services have additional requirements specific to their service:

- 11.9.1. Real-time or live two-way electronic communication utilizing suitable ICT tools (audio or audio visual) between licensed physician and patient or guardian.
- 11.9.2. Appropriate, functioning and well maintained and serviced equipment and devices, as per manufacturer's specifications, to support all diagnostic and tele-consultation needs of the patients.
- 11.9.3. Equipment and devices that are compatible with that of the distant site used to access tele-consultation services.
- 11.9.4. Appropriate information technology support systems to preserve and maintain the medical record/ encounter.



11.9.5. ICT platform that are user-friendly, interactive and flexible to achieve satisfactory patient experience.

#### 11.10. Payment Mechanism

Payment mechanism for tele-consultation services must be in accordance with the Standard Provider Contract as applicable to the tele-counseling services, DOH Mandatory Tariff and associated Claims and Adjudication Rules and the Coding Manual; all documents are available at the DOH website in Data Dictionary (<a href="https://www.doh.gov.ae/en/Shafafiya/dictionary">https://www.doh.gov.ae/en/Shafafiya/dictionary</a>).



#### 12. Tele-Prescribing-Additional Duties and Requirements

#### 12.1. **Scope**

- 12.1.1. Tele-prescribing healthcare services standard applies to the following:
  - 12.1.1.1. Healthcare facilities that have been licensed by DOH to provide teleconsultation services.
  - 12.1.1.2. Healthcare professionals employed in healthcare facilities authorized to prescribe medications.
  - 12.1.1.3. All diseases and conditions that are suitable to be treated and managed meeting the standard of care through tele-prescribing.
- 12.1.2. Tele-prescription standard does not apply to the below:
  - 12.1.2.1. Medical conditions that require emergency/ urgent care are out of scope of this standard; those patients must be referred to appropriate healthcare facility for face-to-face clinical assessment and management.
  - 12.1.2.2. Medical conditions or diseases that may require in-person encounter to meet the standard of care.
  - 12.1.2.3. Medical conditions that require physical examination for diagnosis or invasive clinical interventions.

#### 12.2. Eligibility Criteria- Diseases & Conditions:

12.2.1. Comprises of prescribing of medications for the purpose of prevention, treatment and cure of diseases and conditions that are suitable for this service. This includes non-emergency & non-urgent medical conditions and conditions for which physical examination and/or invasive clinical diagnostic interventions are required and were performed during a previous face-to-face physical encounter with a health provider.

#### 12.2.2. Exclusions:

- 12.2.2.1. Tele-prescribing for serious medical conditions that require emergency/ urgent care are excluded from this standard; those patients must be referred to appropriate healthcare facility for face-to-face clinical examination.
- 12.2.2.2. Tele-prescribing for medical condition that require physical examination or invasive clinical interventions for diagnosis are also excluded.

# 12.3. Specific Governance, Quality and Training-related Duties of Tele-prescription Providers In addition to the general duties of tele-medicine providers, tele-prescription providers have additional service specific requirements.

- 12.3.1. Tele prescribing of medication (are available to individuals, regardless of age (adults and children via their legal guardian) and gender, who seek to access the services for their healthcare and disease management needs.
- 12.3.2. Tele-prescribing service provider must ensure:
  - 12.3.2.1. Patient Registration & Consent:
  - 12.3.2.2. Register patients and verify patient personal identification information prior to offering the service.
- 12.3.3. Tele prescribing service provider must have:
  - 12.3.3.1. Internal policies and standard operating procedures covering the complete scope of tele-prescribing services.
  - 12.3.3.2. Ensure that its healthcare professionals authorized to prescribe medications using ICT have the relevant trainings or certifications periodically to ensure



- meeting the same quality of clinical standards and code of conduct as in face-to-face prescribing encounters.
- 12.3.3.3. Establish Key performance indicators for tele-prescribing services;
- 12.3.3.4. Ensure availability of service and equal access to patients from distant locations or far to reach areas.
- 12.3.3.5. Report adverse events and medication errors in accordance to DOH applicable standard.
- 12.3.3.6. Store and maintain tele-prescribing encounter records as per applicable federal laws and DOH standards for medical records.
- 12.3.4. The physician tele-prescribing must do so live by using the ICT system located within the facility's premises.
- 12.3.5. The physician must have real-time audio/video communication with the patient before issuing the prescription through tele-prescribing services.
- 12.3.6. The communication and prescribed medication must be captured in the patient's EMR.

  This will be limited to tele prescribing by the physician having access to the patient's existing EMR.
- 12.3.7. Additional Specific Compliance Requirements:
  - 12.3.7.1. The provisions under the DOH Standard Provider Contract that apply to teleprescribing services.
  - 12.3.7.2. Comply with the insurance companies to copy records of the teleprescribing service provider.

#### 12.4. Specific Tele-prescribing Care-Related Requirements

- 12.4.1. Have in place Triage, Care Pathways and an e-prescription system with display of complete dispensation of prescribed medicine:
  - 12.4.1.1. In cases of uncertainty on the suitable treatment plan, the physician must refer the patient to face-to-face consultation prior to prescribing.
  - 12.4.1.2. It is the responsibility of the physician to determine whether a pre-existing face-to-face relationship with the patient is necessary to safely and effectively prescribe medications remotely for the management of a particular medical condition to a specific patient.
  - 12.4.1.3. Triage the patient with respect to the category of service required, medical specialty needed and patient location etc.
  - 12.4.1.4. Establish systems to allow prescribers to add electronic signature on the prescription.
  - 12.4.1.5. Ensure prescription format comply to applicable existing federal laws and DoH standard required format of prescriptions (such as use generic name and drug code).
  - 12.4.1.6. Prescribing of controlled, semi-controlled and narcotic medications must be in accordance with existing federal laws, DOH regulations and applicable systems.
  - 12.4.1.7. Prescribe medications judiciously in line with evidence based clinical/treatment guidelines.
  - 12.4.1.8. Refill of medications for chronic conditions in accordance to applicable federal laws and DOH standards.
  - 12.4.1.9. Ensure providing patient full instructions on his/her medications.



- 12.4.2. Tele-prescribing physician must ensure the transmission & recording of the prescription:
  - 12.4.2.1. Document and record all activities electronically in accordance to applicable federal laws and DOH requirements.
  - 12.4.2.2. Develop appropriate mechanism for transmission of prescription to the associated pharmacy using the same HIS system in a secure and confidential manner.

#### 12.5. Specific Information and Communication Technology (ICT) Requirements

In addition to the general ICT requirements for tele-medicine providers, tele-prescription providers have additional service specific requirements. The ICT system must minimally allow:

- 12.5.1. Equipment of suitable quality, designated for medical use installed and used properly and in manner to guarantee patient safety and patient privacy and confidentiality.
- 12.5.2. Transmission of prescription to the patient in secured and confidential manner.
- 12.5.3. Retrieving tele-prescribing record when required.

#### 12.6. Specific Duties of Pharmacies

- 12.6.1. Medications prescribed via tele-prescribing services are required to be dispensed from DOH licensed pharmacies located in Abu Dhabi.
- 12.6.2. Pharmacists are required to dispense medications as per the applicable Federal laws and DOH standard:
  - 12.6.2.1. The prescriptions should be issued through the HIS system of the facility and submitted electronically to their associated pharmacy with access to their HIS system.
  - 12.6.2.2. In the absence of an associated pharmacy with access to the HIS system, then an original prescription must be issued and collected from the facility.

#### 12.6.3. All pharmacies must:

- 12.6.3.1. Make every reasonable effort to ensure the validity of the prescription.
- 12.6.3.2. Ensure elements of standard prescription format are fulfilled/completed.
- 12.6.3.3. Report medication errors in accordance to DOH relevant standard.

#### 12.7. Monitoring and Evaluation

Tele-prescribing service provider must:

- 12.7.1. Conduct periodic monitoring of service quality parameters by documenting, investigating, performing root cause analyses and resolving patient complaints.
- 12.7.2. Conduct patient satisfaction surveys periodically.



#### 13. Tele-Monitoring Services-Additional Duties and Requirements:

#### 13.1. **Scope**:

- 13.1.1. Healthcare facilities that have been licensed by DOH to provide tele-medical services.
- 13.1.2. Healthcare professionals employed in facilities licensed to provide tele-medical services.
- 13.1.3. All devices and supporting systems used to automatically transmit signals from patients to a central station where abnormalities will trigger a response by healthcare professionals or those that support the monitoring data quality, utilization management review and risk management.

#### 13.2. Eligibility Criteria:

Access to tele-monitoring services must be available to all patients who are clinically eligible to receive these services as determined by the treating physician after a face-to-face assessment in the healthcare facility or directly through a tele-consultation session.

#### 13.3. Duties for Tele-monitoring Service Providers

In addition to the general duties of tele-medicine providers, providers of tele-monitoring services have additional service specific duties.

- 13.3.1. Ensure that tele-monitoring services are offered in at least Arabic and/or English languages.
- 13.3.2. Uphold the principles of consent to also include consent for:
  - 13.3.2.1. Monitoring and sharing of data.
  - 13.3.2.2. Surgical insertion of monitoring devices.
- 13.3.3. Must incorporate clinically relevant tele-monitoring data forms into the Electronic Medical Record.

#### 13.4. Specific Governance and Quality-related Requirements:

In addition to the governance and quality related duties and requirements of tele-medicine providers, teleconsultation providers have additional service-specific requirements.

- 13.4.1. The application or order for the service must be signed and dated by the treating physician and subject to the patient's consent or agreement.
- 13.4.2. Must have evidence to demonstrate the request to install and activate tele-monitoring in the patients home.
- 13.4.3. A Clinical and quality governance systems in place to ensure the quality and safety of tele-monitoring services, and protect the confidentiality and security of medical information during and after data transmission including:
  - 13.4.3.1. Evidence to demonstrate that staff are have adequate capacity to manage the desired frequency of monitoring and interaction of patients as indicated by the treating physician.
  - 13.4.3.2. Written Policy and Standard Operating Procedures (SOP) covering among other things:
    - 13.4.3.2.1. Regular review and adoption of evidence based best practice;
    - 13.4.3.2.2. Patient referral to other healthcare providers as needed, including emergency cases and report these cases to DOH.
  - 13.4.3.3. Policy and procedure for downloading and uploading patient data.



- 13.4.3.4. Policies and procedures regarding clinical documentation that originates from tele-monitoring shall be established in compliance with the facility's legal and risk management oversight requirements.
- 13.4.4. Tele-monitoring service provider must ensure incorporation of the technology and equipment into the normal workflow of clinical processes to maximize integration within the healthcare providers overall clinical governance and oversight of other clinical processes.
- 13.4.5. Tele-monitoring service provider must adopt a systematic approach for measuring quality and clinical outcomes.
- 13.4.6. Tele-monitoring services shall:
  - 13.4.6.1. Specify the number of times, type of control and the method of when and how the patient data is obtained and transferred.
  - 13.4.6.2. Where infrastructure permits and patient location indicates, services should be available in rural and remote areas and customized to meet patient's needs.
- 13.4.7. Risk management plan in case of any emergency that include the escalation and management of a detected error, abnormal reading or patient/carer of patient reported emergency and necessary actions.

#### 13.5. Specific Clinical Care-related Requirements

- 13.5.1. Tele-monitoring service provider must:
  - 13.5.1.1. Consider all satisfactory alternatives and risks to tele-monitoring.
  - 13.5.1.2. Provide tele-monitoring services as part of a structured and well-organized system of clinical care.
  - 13.5.1.3. Undertake a face-to-face evaluation prior to the commencement of telemonitoring services.
  - 13.5.1.4. Regularly review the suitability of the tele-monitoring application and associated risks.
- 13.5.2. Tele-monitoring service providers shall:
  - 13.5.2.1. Determine the clinical suitability of patients for the provision of tele-monitoring services.
  - 13.5.2.2. Make use of healthcare management and referral protocols to ensure patients' needs are met in a timely manner and to ensure continuity of care.
  - 13.5.2.3. Follow evidence based clinical care guidelines for tele-monitoring of patients;
  - 13.5.2.4. Not be solely using tele-monitoring to assess and determine the patient plan of care
  - 13.5.2.5. Adjust the duration and frequency of monitoring in accordance with the expected timeframe for clinical review and patient's need.
  - 13.5.2.6. Ensure that the tele-monitoring generated data is reviewed by a nurse or physician and reported to the treating physician as per their request or on a periodic basis.
- 13.5.3. Assure an agreement with respective providers is in place where a patient is placed in a remote area and needs to be seen immediately.
- 13.5.4. Provision of tele-monitoring service shall include:
  - 13.5.4.1. Face-to-face follow up or direct tele-consultation sessions.
  - 13.5.4.2. Regular monitoring and maintenance of devices used.



- 13.5.5. Treating physician must orient a tele-monitored patient on how to act in case of a medical emergency.
- 13.5.6. Patients are entitled to cease tele-monitoring services at any time.
  - 13.5.6.1. Healthcare providers must ensure written notification is issued and signed by the patient and/or caregiver where discontinuation of the service places the patient at serious risk of deterioration or in case of being admitted to emergency services.
  - 13.5.6.2. A discharge form must be documented at the end of the tele-monitoring period.

#### 13.6. Specific Communication, Education, Orientation and Training Requirements:

In addition to the training requirements of tele-medicine providers, tele-monitoring service providers have additional service specific requirements.

- 13.6.1. Adoption of appropriate, flexible, reliable and secure communication approaches.
- 13.6.2. Provision of adequate communication and education to patients and/or their caregivers to enable them to perform the necessary tasks to benefit from tele-monitoring services to include:
  - 13.6.2.1. A patient feedback loop on the approach and level of communication.
  - 13.6.2.2. Self-identification of a problem or error with the monitoring device and an emergency contact number.
- 13.6.3. Orientation and training the responsible staff to ensure that the provision of telemonitoring services does not compromise patient safety, privacy and the expected quality of care to include but not be limited to:
  - 13.6.3.1. Use of tele-monitoring equipment.
  - 13.6.3.2. Actions to take if the technical and/or environmental factors disrupt the transmission of expected patient data to the facility.
  - 13.6.3.3. Interpretation of monitoring data.
  - 13.6.3.4. Limitations of the technology being used and actions to take in the event of sudden discontinuation of data and information and others as needed.
- 13.6.4. Tailored communication protocols must be in place to ensure the minimum requirement for communication is met and any other factors are accounted for such as literacy, language, security and privacy.

#### 13.7. Specific Technical-Related Requirements

In addition to the technical requirements for all tele-medicine providers, tele-monitoring service providers have additional requirements specific to their service.

- 13.7.1. A system to monitor the performance of the tele-monitoring devices that:
  - 13.7.1.1. Captures reliable and accurate monitoring data by date and time.
  - 13.7.1.2. Issues alerts for abnormal or disrupted patient data.
  - 13.7.1.3. Issues reports of quality and safety performance measures.
- 13.7.2. Protocols and procedures to manage "adverse events" or "system errors".
- 13.7.3. Response protocols for the use of an automated alert system.
- 13.7.4. Testing of all devices used for remote monitoring with the patient prior to use and undertaking all necessary checks.
- 13.7.5. Maintaining all monitoring equipment to a high standard as per the manufacturer's instructions and specifications.



- 13.7.6. Reporting to DOH, as part of DOH Medical Device Post Market Surveillance Program:
  - 13.7.6.1. Any safety issue with a medical device.
  - 13.7.6.2. Any adverse event which has impacted either the patient, device operator or any other person which is attributed to or may be attributed to the use of a medical device.
  - 13.7.6.3. Any quality or technical malfunctions which have or may have the potential to lead to an adverse event.
  - 13.7.6.4. Reporting shall be directly after an adverse event occurs and shall be included on the annual report submitted as per Appendix 1.
  - 13.7.6.5. Report shall be submitted via email to medicaldevices@doh.gov.ae or by fax: 02 419 3643, by downloading and filling the medical device incident report form found on DOH website.

#### 13.8. Specific Technology and Equipment-Related Requirements:

In addition to the technology and equipment related requirements of tele-medicine providers, providers of tele-monitoring services have additional requirements specific to their services. They shall have in place criteria for the procurement of tele-monitoring devices including but not limited to:

- 13.8.1. Safety (including alert features during abnormal/unexpected behavior of device).
- 13.8.2. Quality (monitoring and diagnostic).
- 13.8.3. User compatibility and acceptability.
- 13.8.4. Installation and portability.
- 13.8.5. Means of communication and speed of monitoring.
- 13.8.6. Accuracy and reliability.
- 13.8.7. Durability.
- 13.8.8. Conformity to acceptable International Standards.
- 13.8.9. Robustness.
- 13.8.10. Interoperability.
- 13.8.11. Security, data protection, patient and user authentication (including but not limited to inherent ability identify and restrict/prevent hack attempts, encrypt data during transmission and storage, authentication and authorization of access and privileges, ability to fix weakness (vulnerabilities) within device through controlled mechanism, ability of the device to not introduce new threat to the connected/integrated environment).
- 13.8.12. Reporting capability (for errors, investigation and analysis). Maintenance (testing features, network requirements, hardware and software maintenance, calibration and training).
- 13.8.13. Infection control.
- 13.8.14. Compliance with UAE Laws.



#### Appendix 1-

#### Tele-monitoring Related Activities Report – To be kept by the facility for audit purposes

Annual Report: Tele-monitoring related activities					
Facility Details:	Name: Location: Contact: Type: Hospitals Centers Provision of Health Services - Home healthcare Tele-medicine provider				
Total number of cases who used the tele- monitoring devices during the previous year					
List of the identified clinical indications for which tele-monitoring services were prescribed	List of the most common five indication 1. 2. 3. 4. 5.	ons:			
Any safety issue with the tele-monitoring device.	Yes No If yes, kindly identify:  1. Total number of the cases: ———				
Any breach of the tele-monitoring device	☐Yes ☐ No If yes, kindly identify: Number of times that breaches occurr	red: ———			
Any adverse event which has impacted either the patient, device operator or any other person which is attributed to or may be attributed to the use of a tele-monitoring device.	☐Yes ☐ No If yes, kindly identify: 2. Total number of the cases: ———				
Any quality or technical malfunctions in the tele-monitoring device and/or service, which have or may have the potential to lead to an adverse event.	☐Yes ☐ No If yes, kindly identify: 3. Total number of the cases: ———				
Total number of tele-monitored patients referred to other healthcare providers whose vital signs showed abnormalities and/or triggered alerts indicating the need for referral.	Number of referred cases to obtain specialized care:  List of the most common five indications for referral:  1. 2.	Number of emergency cases identified  List of the most common five indications for referral:  1. 2.			
	3.	3.			



	4.	4.
	5.	5.

Appendix 2- Summary of Legal and DOH Tele-medicine Related-Requirements

Dimension	Element	Tele-Diagnosis	Tele-counseling	Tele-Medical Intervention	Tele-consultation	Tele-Monitoring	Tele-Prescription	
	Licensing	Tele-medicine License	required for all					
	Medical Liability	Required for all to cover any medical errors due to or resulting from tele-medicine services						
General legal requirements As per the Annex to the Cabinet Resolution No.	Operational system	2. Adequate bandw 3. Alternative meth 4. Back-up power s 5. Servers and back 6. Internet technolo 7. High-quality telep 8. Provision of the r Operational system in p 1. A system to mon	<ol> <li>Adequate bandwidth.</li> <li>Alternative methods of communication between provider and user.</li> <li>Back-up power system.</li> <li>Servers and back up servers to be located in the UAE.</li> <li>Internet technology and systems that respond to the needs for the tele-medicine service provided.</li> <li>High-quality telephone communication systems and systems for recording of telephone conversations.</li> <li>Provision of the requisite technology and equipment to record and document the provided tele-medicine services.</li> </ol> Operational system in place that includes and/or achieves the following:					
40, 2019 Governing Tele- health services	·	<ol> <li>Process and syst</li> <li>Necessary mech</li> <li>System in place</li> <li>Personal identific</li> </ol>	<ol> <li>Governance &amp; management systems, protocols and guidelines defining roles &amp; responsibilities.</li> <li>Process and systems in place to save &amp; document the records &amp; personal data of patients receiving tele-medicine services.</li> <li>Necessary mechanisms and structures in place to protect the privacy of the patient and tele-medicine encounter.</li> <li>System in place to protect the confidentiality of patient records.</li> <li>Personal identification system in place and as per the specifications of the local health authorities.</li> </ol>					
	Patient's rights and responsibilities Training	<ol> <li>Patients consent to receive the service;</li> <li>Patient's consent to have voice &amp; video recording;</li> <li>Patient's responsibility to provide full and accurate personal identification information.</li> </ol> Qualified manpower with the technical, ICT and legal training appropriate for the tele-medicine services provided.						
Service Specific Legal Requirements	Training	Refer to the Annex to the Cabinet Resolution No. 40, 2019 Governing Tele-health services.						
			DOH Regulat	ory Requirements				
General	Governance	i. Industry good practice Standard Operating Procedures for the following: a. internet, video & bio data monitoring;	i. Quality Committee (for facilities with > 10 professionals); ii. Industry good practice Standard Operating	ii. Privileging of staff on tele- medical interventions; iii. Quality Committee (for facilities with > 10 professionals);	i. Quality Committee (for facilities with > 10 professionals); ii. Industry good practice Standard Operating Procedures for the following:	i. Quality Committee (for facilities with > 10 professionals). ii. Industry good practice Standard Operating	i. Industry good practice Standard Operating Procedures for the following: a. Telephone, internet & video. monitoring;	



		b. Transfer of images and data;	Procedures for the following: a. Telephone, internet, video & bio data monitoring; b. Transfer of images and data;	iv. Industry good practice Standard Operating Procedures for the following: a. Video streaming b. Data exchange;	a. Telephone, internet, video & bio data monitoring; b. Tele-referral after tele- counseling c. Prescribing drugs d. Issuing sick leaves e. Ordering diagnostics	Procedures for the following:  a. Bio data monitoring.  b. Escalation & Management protocols for telemonitoring emergencies.	b. Prescribing drugs c. Transfer of prescription.
	Personal Identification & Data Management is assured by the Provider	Usual process and requidentification to be follor originating facility.	•	Usual process and requirements for patient identification to be followed by the facility	i. Patient identif as Emirate ID not issued) an ii. Patient legal g status as legal required include where an EID establishing re iii. Data security a ADHICS, DOH Requirements iv. Data confiden applicable forr Federal laws. v. Risk managem	Patient identification & recording of patient identifiers such as Emirate ID number (or passport number where an EID is not issued) and Date of Birth or Medical record number. Patient legal guardian identification & establishing their status as legal guardian. A minimum of three identifiers are required including: Emirate ID number (or passport number where an EID is not issued) and document identity establishing relationship and legal authority as guardian. Data security and protection protocols are compliant with ADHICS, DOH Data Standards, Procedures and Requirements.  Data confidentiality, privacy and patient consent protocols an applicable forms are compliant with DOH Standards and UAE	
Technological &	Information Technology (IT)	i. IT operations: adequate resources for planning, setting up operation and maintenance of information and communication infrastructure; ii. User support resources for employees & patients					
Security considerations	Communication	Technologies and internet systems comply with ADDA requirements;     iii. Medical, including bio-monitoring devices, comply with DOH requirements.					
	Security	Comply with all applicable provisions of ADHICS Standard, and any future Security Standards or Policies that may impact the way in which data is gathered, processed, accessed, utilized, shared, stored and/or destroyed.					



	Infrastructure	<ul> <li>i. Workstation &amp; room design satisfy DOH Guidelines for Health Facilities Design;</li> <li>ii. Hardware, including for communication &amp; internet access, with good industry standard servers, physical &amp; logical security measures;</li> <li>iii. Environmental &amp; occupational health &amp; safety compliant with DOH requirements;</li> <li>iv. Good industry standard telephone system including call recording &amp; integration with patient management system, where possible;</li> <li>ii. Case management &amp; tele-referral system &amp; tele-medical measuring equipment, suited to the type of services to be offered by the provider.</li> </ul>					
Service Operation Considerations	Quality assurance & measurement	i. Guidelines to describe the purpose of and need for using tele-diagnostic services;  i. Guidelines describe the purpose of need for us tele-counse services;	e based clinical and guidelines; ing ii. Training &	i. Standardized treatment protocols using evidence based clinical guidelines; ii. Training & certification of professionals & staff. iii. Evidence of accredited telemedicine training program to be provided on application for licensure & for audit purposes. iv. Accreditation of training programs may be obtained from internationally reputable bodies such as, but not limited to, the American Telemedicine Association; v. Metrics such as for communication, patient satisfaction and	i. Evidenced based tele-monitoring protocols. ii. Training & certification of professionals & staff. iii. Evidenced of accredited training program to be provided on application for licensure & for audit purposes. iv. Accreditation of such training programs may be obtained from internationally reputable bodies such as, but not limited to, the American Telemedicine Association; v. Metrics for monitoring patient satisfaction & managing patient conditions may be considered.	i. Evidence-based clinical guidelines/ Standardized treatment protocols using evidence based clinical guidelines (if issued as part of tele-counseling); ii. Training & certification of professionals & staff. iii. Evidence of accredited telemedicine training program to be provided on application for licensure & for audit purposes. iv. Accreditation of training programs may be obtained from internationally reputable bodies such as, but not limited to, the American	



		tele-referral may	Telemedicine
		be considered.	Association;
			v. Metrics such as
			for
			communication,
			patient
			satisfaction &
			tele-referral may
			be considered.

#### Appendix 3- Annexure to Cabinet Decision 40 for 2019 Governing Tele-health services:



## المعق المرفق بقرار مجلس الوزراء رقم (40) لسنة 2019 بشان المسؤولية الطبية بشأن المانعة التنفيذية للمرسوم بقانون التعادي رقم (4) لسنة 2016 بشأن المسؤولية الطبية

#### ضوابط وشروط تقديم الغدمات الصحية عن بعد

#### أولاً: التعاريف

الاستشارة الطبية عن بعد: استشارة عبر استخدام تقنيات المعلومات والاتصالات، لتقديم النصح حول أفضل السبل للتعامل مع الحالة الصحية التي تتم بين طبيب وطبيب آخر أو طبيب ومريض في الحالات التي لا يكون فيها المريض والطبيب في نفس المكان.

وصف العلاج عن بعد: قيام الطبيب المختص بوصف العلاج في الحالات التي لا يكون فيها الطبيب والمريض في نفس المكان عبر استخدام تقنيات المعلومات والاتصالات بعد إجراء التشخيص عن بعد دون عمل الكشف السريري على المريض أو وصف العلاج عن بعد بناة على تشخيص تم بالأسلوب السريري التقليدي.

التشخيص عن بعد: تحديد ماهية المرض أو الحالة الصحية للمريض عبر استخدام تقنيات المعلومات والاتصالات من مقدم الخدمة الصحية.

المراقبة الطبية عن بعد: الحصول على العلامات الحيوية ومراقبة حالة المريض عبر استخدام تقنيات المعلومات والاتصالات من مقدم الخدمة الصحية.

التدخل الطبي عن بعد: أي عمل طبى تدخلي عن بعد باستخدام تقنيات المعلومات والاتصالات.

#### ثانياً: شروط وضوابط تقديم الخدمات الصحية عن بعد

- الضوابط العامة: وهي التي تطبق على جميع مجالات تقديم الخدمات الصحية عن بعد.
  - الضوابط المتعلقة بالمنشأة التي تقدم الخدمات الصحية عن بعد:
  - يجب على المنشأة التي تقدم الخدمات الصحية عن بعد الالتزام بما يأتي:
  - أ. الحصول على ترخيص من الجهة الصحية بالسماح بتقديم هذه الخدمات.





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- ب. توفير شبكة تقنية متكاملة تضمن حسن تقديم الخدمة الصحية عن بعد حسب المعايير التي
   تحددها الجهة الصحية.
  - ج. توفير نطاق تريدي كاف.
  - د. توفير طرق بديلة المتواصل بين مقدم الخدمة ومتلقيها.
    - ه. توفير نظام طاقة احتياطي.
- و. توفير (خوادم-servers) داخل الدولة لتخزين وحفظ المعلومات ومكان احتياطي لـه (backup).
  - ز. توفير تقنيات وأنظمة انترنت تستجيب لمتطلبات تقديم الخدمة الصحية عن بعد.
    - ح. الامتثال لمعايير جودة عالية بخصوص أنظمة الهاتف وتسجيل المكالمات.
  - ط. توفير الأجهزة التقنية اللازمة لتسجيل وتوثيق الخدمات الصحية التي تقدم عن بعد.
- ي. توفير الموارد البشرية المؤهلة لتقديم الخدمة الصحية عن بعد، من خلال إخضاعهم لتدريب خاص يتناسب مع طبيعة الخدمة الصحية التي تقدم عن بعد، بما في ذلك: التدريب في الجوانب الفنية والتقنية والقانونية وفقاً لما تقرره الجهة الصحية في هذا الشأن.
  - ك. توفير غطاء تأميني عن الأخطاء الطبية الناشئة عن تقديم تلك الخدمة أو بسببها.
    - ل. أن يكون نظام العمل المعتمد في المنشأة محققاً لما يأتي:
  - 1) توفير أدلة على وجود نظام للرصد والرقابة والإبلاغ عن جودة وسلامة مقاييس الأداء.
- توفير الوسائل اللازمة لحفظ السجلات الكاملة والبيانات الخاصة بالأشخاص الذين تقدم
   لهم الخدمة الصحية عن بعد وتوثيقها.
- 3) توفير نظام لحماية البيانات والسجلات الخاصة بالخدمة الصحية عن بعد وعدم السماح بالاطلاع عليها من غير الأشخاص المخول لهم بذلك.
- 4) توفير الآليات اللازمة لحماية خصوصية الأشخاص الذين تقدم لهم الخدمة الصحية عن بعد.
  - 5) وضع نظام للمحافظة على سرية ملفات المرضى.
- 6) وضع أدلة وإجراءات لتنظيم تقديم الخدمات الصحية عن بعد، بحيث تحدد فيها الأدوار والمسؤوليات في إطار نظام للحوكمة.





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7) وضع نظام لتحديد هوية الشخص الذي تقدم له الخدمة الصحية عن بعد، والوثائق اللازمة لذلك وفقاً لما تحدده الجهة الصحية.

#### 2. الضوابط المتعلقة بمتلقى الخدمة:

يجب على متلقي الخدمة الصحية عن بعد الالتزام بما يأتي:

الموافقة على التسجيل الصوتي والمرئي وغيره.

ب. الموافقة على تلقي الخدمة.

ج. التعريف عن نفسه وإعطاء معلومات صحيحة وكاملة.

- الضوابط الخاصة: وهي التي تتعلق بكل خدمة من الخدمات الصحية التي تقدم عن بعد، كل على حدة، وذلك بحسب ما يأتي:
  - 1. الضوابط المتعلقة بخدمة التشخيص عن بعد:
- أ. يكون تقديم الخدمة بعد إبرام اتفاق بين طالب الخدمة ومقدمها، ويحدد فيه إجراءات وأساليب
   التعامل بين الطرفين في هذا المجال.
  - ب. يجب مراعاة تحقيق الضوابط التالية الخاصة بسلامة المريض:
  - 1) أن يتم تقديم الخدمة من خلال مركز تشخيصي مرخص له في الدولة.
- 2) تمكين مقدم الخدمة من الاطلاع على الصور الطبية السابقة للمريض والتقارير المتعلقة بها بغرض الوصول إلى التشخيص الدقيق وإعداد التقرير اللازم.
- 3) تمكين مقدم الخدمة من الحصول على كل البيانات الصحية المتعلقة بالمريض قبل إعداد تقريره.
- 4) سهولة التواصل مع الطبيب الذي أعد تقرير التشخيص عن بعد، من خلال الهاتف أو أي وسيلة اتصال أخرى متاحة لمناقشة التقرير عند الحاجة.
  - ج. يجب مراعاة تحقيق الضوابط التالية الخاصة بتبادل البيانات والتقارير:
- 1) الحصول على موافقة المريض قبل تحويل بياناته إلى أي منشأة أخرى بغرض القيام بعملية التشخيص عن بعد.





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- 2) أن يكون تحويل البيانات في حدود الحاجة التي تتطلبها الحالة الصحية للمريض، وبما يضمن إنجاز عملية التشخيص عن بعد على أحسن وجه.
- 3) وضع إجراءات دقيقة بشأن كيفية تحويل بيانات المريض وحفظها وتخزينها وحمايتها والمحافظة على سربتها.

#### 2. الضوابط المتعلقة بخدمة الاستشارة عن بعد:

تخضع الاستشارة عن بعد للضوابط الخاصة التي تضعها الجهة الصحية، وفي جميع الأحوال يكون المهني الصحي الذي يتعامل مباشرة مع المريض مسؤولاً عن أي عمل من أعمال الرعاية الصحية التي يقوم بها تجاه المريض.

- 3. الضوابط المتعلقة بوصف العلاج عن بعد:
- أ. يتم وصف العلاج عن بعد من قبل طبيب مرخص من الجهات الصحية في الدولة، ويعمل في منشأة مرخصة لتقديم الخدمات الصحية عن بعد.
- ب. يجب على الطبيب الذي يتولى وصف العلاج عن بعد أن يقوم بفحص المريض إلكترونياً، وذلك عن طريق استخدام التكنولوجيا الإلكترونية مع التمسك بالمعايير في مستوى الرعاية الصحية داخل الدولة.
  - ج. يجب توثيق الملفات والمستندات وفقاً للقواعد واللوائح المعمول بها.
- د. يجب أن يكون وصف العلاج ناتجاً عن تشخيص يضمن عدم وجود موانع لوصف العلاج وتلقيه، كما يجب التأكد من أن المريض قادر على استيعاب المخاطر وملم بالفوائد المرتبطة بالعلاج، وإلا وجب إحالة المريض إلى طبيب الرعاية الصحية للفحص السريري.
- ه. على الطبيب مناقشة الخطة العلاجية مع المريض إلا إذا كانت حالته الجسدية أو الذهنية لا تسمح بذلك.
  - و. يتم وصف الأدوية وفقاً للتشريعات المعمول بها في الدولة.
- ز. يجوز للطبيب وصف العلاج دون التقيد بضوابط وصف العلاج عن بعد المتعلقة بالتشخيص
   ومناقشة العلاج مع المريض وذلك في الحالات الآتية:
- إذا تم التشاور مع طبيب آخر لديه علاقة مباشرة مع المريض مع توفير الإشراف المستمر للعلاج.





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2) حالة المناوية أو عبر التغطية عن طريق الهاتف، بحيث يكون للطبيب الذي يصف العلاج اطلع على سجلات المريض الصحية.

#### 4. الضوابط المتعلقة بالمراقبة الصحية عن بعد:

- أ. تقديم طلب كامل لتركيب وتفعيل خدمة المراقبة عن بعد في المنزل أو المكان الذي يوجد فيه المريض (العميل).
- ب. تقديم طلب أو أمر خدمة المراقبة عن بعد موقعاً ومؤرخاً من قبل الطبيب المعالج للمريض (العميل).
  - ج. التأكد من أن بيانات المراقبة عن بعد يتم جمعها بشكل موثوق ودقيق.
    - يجب ختم البيانات بالتاريخ والوقت لحمايتها من التغيير.
  - ه. التأكد من إدراج البيانات المراقبة في السجلات الطبية الإلكترونية للمريض (EMR).
    - و. لا يجوز تكرار مراقبة البيانات السريرية للمريض من قبل أي مزود خدمة آخر.
      - ز. الحفاظ على وثائق النظام واستخدام المعلومات.
- ح. يجب مراجعة البيانات من قبل الممرض أو الطبيب المساعد، ويكون كل منهما مسؤولاً عن
   الإبلاغ عن البيانات للطبيب الذي يتولى إصدار الوصفات الطبية.
  - ط. تقديم التقارير الدورية المقررة حول بيانات المريض إلى الطبيب.
  - ي. يحق للمريض إيقاف خدمة المراقبة عن بعد من المنزل في أي وقت.
    - ك. يجب توفر مقدمي خدمة المراقبة عن بعد على مدار الساعة.
- ل. تشمل خدمة المراقبة عن بعد عدد المرات، ونوع المراقبة، والتوقيت، وطريقة وكيفية الحصول
   على البيانات، ونقلها، (على سبيل المثال: هل يتم تحميل بيانات نتائج فحص السكر يومياً،
   أسبوعياً، أو على الفور ...)
  - م. تحديد توقيت الاستجابة المتوقعة لبيانات المرضى.
- ن. تحديد سياسة التغطية خارج ساعات الخدمة لتحميل البيانات واستخدام نظام الإنذار الآلي،
- س. يجب وضع إجراءات للتعامل مع "الأحداث غير المرغوب فيها" وأن تكون متاحة للأشخاص
   المعنيين.





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- ع. يجب توفير معايير المراقبة للتحليل البدوي والإلكتروني كل على حدة ومعاً.
- ف. التأكد من أن كافة الأجهزة المستخدمة للمراقبة عن بعد تعمل بشكل جيد.
- ص. ينبغي ألا تسبب أجهزة الاستشعار أي ضرر أو تهيج لجلد المريض، ويجب ألا تسبب له ضيقاً أثناء النوم، أو تشكل خطراً عند البلع.
  - ق. تحديد بروتوكولات الاستجابة للإنذارات من نظام المراقبة عن بعد.
- ر. توفير وصيانة معدات المراقبة عن بعد، وتقع على عاتق مقدم الرعاية المنزلية أو المستشفى مسؤولية ذلك.

#### الضوابط المتعلقة بالتدخل الطبي عن بعد:

- أ. يخضع التدخل الطبي عن بعد للضوابط الخاصة التي تضعها الجهة الصحية.
- ب. في جميع الأحوال يجب وجود مهني صحي بجانب المريض يكون قادراً على التدخل عند الحاجة في حالة تعطل الأجهزة التقنية المسيرة عن بعد.





#### Appendix 4:

# The Appendix Enclosed With Resolution No. (40) of 2019 of the Cabinet, Concerning the Executive Bylaw of the Federal Decree-Law No. (4) of 2016, Concerning Medical Liability

The Regulations and Conditions for the Provision of Telehealth Services\*

#### I. <u>Definitions</u>

**Tele-medical counseling:** A consultation that is given via information and telecommunication technologies, for giving advice about the best means for dealing with a medical case, as taking place between a physician and another physician, or a physician and a patient in the cases in which the patient and the physician are not in the same place.

**Tele-prescription of Treatment:** A situation in which the specialized physician would prescribe the treatment in the cases in which the patient and the physician are not in the same place, via information and telecommunication technologies, after telediagnosis without the clinical examination of the patient, or a situation in which the specialized physician would prescribe treatment remotely based on a diagnosis that has been made using the conventional clinical method.

**Tele-diagnosis:** Determining what is the disease or the medical case of the patient via information and telecommunication technologies by the healthcare service provider.

**Tele-medical Monitoring:** Obtaining the vital signs and monitoring the patient's condition via information and telecommunication technologies by the healthcare service provider.

**Tele-medical Intervention:** Any interventive medical procedure that is taken remotely via information and telecommunication technologies.

#### II. The Conditions and Regulations for the Provision of Telehealth Services

- **General Regulations:** These are the regulations that are applicable to all the fields of the provision of telehealth services.
  - 1. The regulations related to the facility that is providing telehealth services:

A facility that is providing telehealth services shall comply to the following:

- a. To obtain a license from the health authority for permitting the provision of such services.
- b. To provide an integrated network technology that ensures the good provision of the telehealth service as per the criteria that are set forth by the health authority.
- c. To provide a sufficient frequency band.



- d. To provide alternative means of communication between the service provider and the service receiver.
- e. To provide a stand-by power system.
- f. To provide servers in the UAE for storing and keeping information with a backup of such information.
- g. To provide Internet systems and technologies that meet the requirements for the provision of the telehealth service.
- h. To comply to high quality standards regarding telephony and call recording systems.
- i. To provide the necessary technical devices for the recording and documentation of provided telehealth services.
- j. To provide the qualified human resources for the provision of the telehealth service, by having them receive a special training that is consistent with the nature of the telehealth service that is being provided, including: training on the technical and legal aspects as resolved by the health authority in this regard.
- k. To provide an insurance cover for the medical errors arising from or on the occasion of the provision of such service.
- I. The system of work applied by the facility shall meet the following requirements:
  - 1) To provide evidences for the existence of a system for the observation of, monitoring, and reporting the quality and safety of performance benchmarks.
  - 2) To provide the necessary means for keeping the full records and the details of the persons to whom the telehealth service is being provided, and for the documentation thereof.
  - 3) To provide a system for the protection of the details and records of the telehealth service that is being provided and to not permit access thereto by other than the persons who are authorized to do so.
  - 4) To provide the necessary mechanisms for the protection of the persons to whom the telehealth service is being provided.
  - 5) To set forth a system for maintaining the confidentiality of the patients' files.
  - 6) To set forth guides and procedures for regulating the provision of telehealth services, in which roles and responsibilities are specified within a governance framework.
  - 7) To set forth a system for identifying the person to whom the telehealth service is being provided, and the documents necessary for such, as specified by the health authority.
- 2. The regulations related to the service receiver:

The receiver of a telehealth service shall comply to the following:

- a. To consent audio and visual recording, etc.
- b. To consent to receive the service.
- c. To introduce himself and give true and complete information.
- **Special Regulations:** These are the regulations that are related to each and every telehealth service that is being provided, according to the following:
  - 1. The regulations related to the service of telediagnosis:



- a. The service shall be provided after entering an agreement between the service requester and service provider, in specifying the procedures and means of dealing between both parties in this regard.
- b. The following regulations shall be observed as in relation to patient safety:
  - 1) The service shall be provided by a diagnosis center that is licensed in the UAE.
  - 2) The service provider shall be enabled to gain access to the prior medical images of the patient and the reports related thereto in order to arrive to an accurate diagnosis and to prepare the necessary report.
  - 3) The service provider shall be enabled to obtain all the medical data of the patient prior to preparing the report thereof.
  - 4) It shall be easy to communicate with the physician who prepared the telediagnosis report, by phone or any other means of communication that is available for the discussion of the report when needed.
- c. The following special regulations shall be observed as in relation to the exchange of data and reports:
  - 1) The patient's consent shall be obtained prior to forwarding his data to any other facility for performing the telediagnosis process.
  - 2) Data shall be forwarded within the limits of the requirement of the medical case of the patient, and in what would ensure the completion of the telediagnosis process in the best manner
  - 3) To set forth accurate procedures about how the patient's data are forwarded, kept, stored, protected, and kept confidential.
- 2. The regulations related to the service of telecounseling:

  Telecounseling is subject to the special regulations that are set forth by the health authority. In all cases, the healthcare professional who is directly dealing with the patient shall be responsible for every healthcare act he is doing in service of the patient.
- 3. The regulations related to the teleprescription of treatment:
  - a. The treatment shall be prescribed remotely by a physician who is licensed by the health authorities in the UAE and who is working for any facility that is licensed to provide telehealth services.
  - b. The physician who is prescribing the treatment remotely shall examine the patient via electronic means using electronics technology, along with adherence to the criteria of the standard of healthcare in the UAE.
  - c. The files and documents shall be archived in accordance with the rules and codes in force.
  - d. The prescription of the treatment shall be made as a result that ensures that there is noting that wound hinder the prescription and administration of the treatment. Furthermore, it should be verified that the patient is able to comprehend the risks and is aware of the benefits associated with the treatment, failing such, the patient shall be referred to the healthcare physician for clinical examination.
  - e. The physician shall discuss the treatment plan with the patient, unless if his physical or mental condition does not permit so.

<sup>\*</sup>This is a translation of the Arabic version. In case of any issue, the Arabic version shall prevail.



- f. Medications shall be prescribed in accordance with the legislations in force in the UAE.
- g. The physician may prescribe the treatment without compliance to the regulations for the prescription of treatment remotely as in relation to diagnosis and the discussion of the treatment with the patient in the following cases:
  - 1) If consultation was made with another physician who has a direct relationship with the patient, with the provision of the ongoing supervision of the treatment.
  - 2) In the case of working shifts or coverage via phone, whereby the physician who is prescribing the treatment has inspected the medical records of the patient.

#### 4. The regulations related to telemedical monitoring:

- a. To submit a full application for the installation and activation of the service of telemonitoring at home or the place at which the patient (the client) is available.
- b. To submit an application or an order for the service of telemonitoring, signed and dated by the attending physician in charge of treating the patient (the client).
- c. To ensure that telemonitoring data are being collected reliably and accurately.
- d. The data shall be timestamped and date-stamped for the protection thereof from alteration.
- e. To ensure the inscription of monitoring data into the electronic medical records (EMR) of the patient.
- f. The clinical data of a patient may not be monitored repeatedly by any other service provider.
- g. The documents of the system and the use of information shall be safely kept.
- h. The data shall be reviewed by the nurse or the assistant physician, who shall both be responsible to report the data to the physician who is issuing the medical prescriptions.
- i. To submit the required periodic reports about the patient's data to the physician.
- j. The patient may stop the service of telemonitoring from home at any time.
- k. Service providers of telemonitoring shall be provided all around the clock.
- I. The service of telemonitoring includes the number of times, the type of monitoring, the timing, and how data are collected and transferred (for example, are the data of diabetic test results being uploaded every day, weekly, immediately, etc.).
- m. To specify the timing of the anticipated response to the patients' data.
- n. To set forth the policy of coverage outside service hours for uploading the data and the use of the automatic alerting system.
- o. Procedures shall be set forth for dealing with "undesired events" and they shall be made available to the concerned persons.
- p. Monitoring criteria for manual and electronic testing, separately and altogether, shall be provided.
- q. To ensure that all the devices that are used for telemonitoring are operating well.
- r. Sensing devices shall not cause any harm or irritation to the patient's skin, and shall cause no disturbance to the patient while sleeping, and shall cause no danger when swallowing.
- s. To set forth the protocols of response to the alerts that are received from the telemonitoring system.
- t. To provide and maintain the equipment of telemonitoring. The hospital or the provider of homecare shall be responsible for this.

<sup>\*</sup>This is a translation of the Arabic version. In case of any issue, the Arabic version shall prevail.



- 5. The regulations related to telemedical intervention:
  - a. Telemedical intervention shall be subject to the special regulations that are set forth by the health authority.
  - b. In all cases, there shall be, beside the patient, a healthcare professional who shall be able to intervene when needed in case a fault occurs in the operation of the telecontrolled technical devices.

<sup>\*</sup>This is a translation of the Arabic version. In case of any issue, the Arabic version shall prevail.



#### Appendix 5:

1. Licensing requirements	
1.1 Facilities should specify the particular tele-medicine service they will be providing that meet licensing requirements.	
2. Governance & Quality Related Requirements	
2.1 DOH licensed tele-medicine service providers must have the right physical infrastructure for the tele-medicine areas to preserve the privacy, access to and confidentiality of case  2.2Providers of tele-medicine services must have in place data management systems and	
protocols that maintain the confidentiality of gathered personal/patient information and that access to, use, sharing and transmission and reporting of such data complies with relevant DOH regulations	
<ul> <li>2.3 Policies and procedures in place for at least the following elements:</li> <li>2.3.1 Collaborations, affiliations, agreements and/or contracts with other healthcare providers in the healthcare system to support delivery and continuity of care.</li> <li>2.3.2 Managing image sharing and transmission.</li> </ul>	
2.4 Tele-monitoring Related Activities Report - To be kept by the facility for audit purposes	
2.5 Evidence-based guidelines to describe the purposes of the facility's tele-medicine services, including scope and specifications;	
2.6 Must have a patient referral system: 2.6.1 Patients may be referred to other providers in cases such as but not limited to triage where the advice/decision of a physician/specialized physician is required, or for face-to-face consultation or other specific tele-health service.	
2.7 The facility ensures that only tele-medicine trained and certified staff are granted the privilege to provide telec services,	
2.8 The healthcare provider maintains the highest ethical standards and ensures that every member of their staff behaves at all times with courtesy, respect, dignity and discretion in their dealings with Patients.	



3. ICT requirements	
5. 10. requirements	
<b>3.1</b> Availability of the right ICT infrastructure and supportive environment for the tele-medicine service provided including:	
3.2 Information and communication technology (ICT) Policies, procedures and systems to assure the safe, effective and secure transmission of health information and its confidentiality that meet DoH and Digital Authority requirements must be in place and implemented.	
3.3 Regular monitoring and assessment of the ICT infrastructure and supportive environment to assure their effectiveness;	
3.4 Procedures in place to ensure security and protection of the patient health records.	
3.5 They have the appropriate equipment & devices to support transmission and receipt of all diagnostic and assessment needs of the patients	
3.6 The equipment and devices are compatible with that of the distant site providing telemedicine services;	
3.7 Patients test results and health data when used to support tele-medicine services are of high quality, clarity, and legibility including all images.	
4 Training requirements	
4.3 Staff training guidelines on the secure use of supportive technologies;	$\dashv$
4.3.1 It assess its staff training needs and provides training in tele-medicine technologies, where identified as necessary; 4.3.2 The facility must maintain an up-to-date record of its staff telemedicine training, whenever conducted.	
5 Patient's rights and responsibility	
5.3 Patient's verbal or electronic consent for assessment and receipt of treatment and/or surgery, the creation of a medical record, access to patient's information and for insurance purposes.  5.3.1 Verbal consent is to be recorded and/or documented on the patient's records;	
1000100,	



5.3.2 Electronic consent can be obtained via technology-enabled communication media;	
6 Specific Duties of Tele-medical intervention providers	
6.3 Ensure that the physician performing the tele-medical intervention is licensed by DOH, if located in Abu Dhabi, or by the respective regulatory authority in the UAE or the country specific regulator, if located outside of UAE.	
6.4 Ensure that there is a licensed health professional next to the patient at all times ready to intervene in the event of failure in the tele robotic system, including handling the robot on the intervention site.	
6.5 Ensure that the physical infrastructure for the tele-medical intervention service areas complies with the DOH Guidelines for Health Facilities Design;	
6.6 Ensure that any robotic system used for in the provision of the tele-medical intervention service is an assistive technology, thus not replacing the healthcare professional (i.e. autonomous) but is operated and controlled by the healthcare professional.	
6.7 Ensure that each room used for tele-medical intervention service has the robotic equipment and instrumentation that is specific to the service to be provided in that room (i.e. Tele-robotic surgery and the particular type of tele-robotic surgery or Tele-robotic investigation and the particular type of tele-robotic investigation);	
6.8 Must protect the privacy concerns of the patient and the confidentiality and security of their medical information and records at the tele-medical intervention site and during transmission to the operating physician;	
6.9 A Tele-robotics Program and leadership team with a minimum of a Director, a healthcare professional trained and experienced in tele-robotic services, robotics Clinical Head Nurse (if it is for tele-robotic surgeries), robotics coordinator and a lead for utilization and performance monitoring and metrics data collection.	
6.10 The tele-medical intervention system is a clinically approved system as per the international certification and/or approval agencies recognized by the Ministry of Health and Prevention of the United Arab Emirates.	
6.11 Same systems at the site of the surgeon controlling the system and the site of the robotic system;	



6.12 Same systems at the site of the surgeon controlling the system and the site of the robotic system;	
6.13 Real-time or live two-way electronic communication utilizing suitable ICT tools (including video) to ensure low delay in communication between the surgeon controlling the system and the robotic system;	
6.14 Appropriate, functioning and well maintained and serviced equipment and devices, as per manufacturers' specifications, to support all tele-medical intervention-related needs of the patients;	

<sup>\*</sup> This is in addition to general audit checklist