

Annex (48)

Telehealth service Requirements

In addition to annex 3 for Management of Medical Information and Records and annex 22 for Tele-medicine centers in Health Requirements, Technical Standards and Safety Requirements to be Available in the Premises and Fittings of Healthcare Facilities issued by NHRA.

Telehealth services include, but are not limited to, scheduling appointments, assessment, providing medical advice, treatment, therapy, diagnostics, monitoring chronic conditions, counselling, and prescribing and dispensing of medication.

To fulfil this Standard, NHRA has placed a high priority on enabling telehealth, and adopted seven main components aimed at providing a distinctive model for telehealth services, including:

- 1) providing medical consultations using telehealth services.
- 2) using electronic medical files to access patient's family history.
- 3) prescribing medications via telemedicine based on an approved list of medication, which is allowed to be prescribed via telehealth services; more information regarding Telemedicine Dispensing Procedure, is provided on this link:

- https://www.nhra.bh/Departments/PPR/MediaHandler/GenericHandler/documents/departments/PPR/Pharmaceutical%20Facilities/PPR_Procedure_Telemedicine%20Dispensing%20Procedure_V1.1_20200723.pdf

- 4) raising awareness on how to use medical devices for initial diagnosis such as thermometer, blood glucose monitoring devices, devices for self-measurement of blood pressure and other essential biomarkers.
- 5) studying the optimal options for the application of the model to provide the telehealth services for free.
- 6) developing packages that incentivize the use of telemedicine services; and
- 7) developing the appropriate legislative framework for the provision of telemedicine services in the Kingdom of Bahrain.

Telehealth is divided into five key areas:

- a) Teleconsultation
- b) Telediagnosis
- c) Telemonitoring (remote patient monitoring)
- d) Mobile Health
- e) Telepharmacy

1. PURPOSE

- 1.1.To set out the minimum Standards for provision of Telehealth services within NHRA licensed Health Facilities.
- 1.2.To establish minimum requirements for NHRA licensed physicians to provide efficient, secure, safe, and high-quality Telehealth services.
- 1.3.To support Healthcare Innovation and Health Technology development in the field of medicine.
- 1.4.To set out the minimum requirements for monitoring and evaluation of Telehealth services provided by NHRA licensed health facilities.
- 1.5.To set out the exclusions for the provision of Telehealth services.
- 1.6. To provide citizens with medical consultations 24/7 through hundreds of thousands of doctors, specialists, and medical consultants across the globe. This will be facilitated by smart application. Our goal is to transform the medical system to bring doctors closer to individuals, enhance awareness and utilize top medical minds globally to serve the health of our citizens.

2. These standards apply to all NHRA licensed healthcare professionals and health facilities providing telehealth services.
3. Exclusion for telehealth services:
 - 3.1. Emergency cases where immediate life threatening intervention or referral is required.
 - 3.2. Prescribing of narcotic, controlled or semi-controlled medication.
 - 3.3. Video recording during patient consultation and storage of patient video files.
 - 3.3.1. NHRA may grant exceptions upon written request to record video on an ad hoc or time limited basis for physician education and quality improvement purposes.
 - 3.3.2. The written request for exceptions must include the following:
 - i. Purpose.
 - ii. Clear justification.
 - iii. Protocol for capturing, anonymising, pseudonymising, storing, using video files.
 - iv. Security measures (including encryption), backup plan to protect and safeguard video files.
 - v. Patient consent form for time limited storage of video consultations for physician, education, and quality improvement purposes.
 - vi. Duration for storage of information and measures for deletion
 - vii. Risk assessment plan for potential breaches and response measures.
4. Standards for Telehealth Services
 - 4.1. Provision of Telehealth - HEALTH FACILITY REQUIREMENTS
 - 4.1.1. A health facility seeking to provide telehealth service(s) must comply with Bahrain laws and Regulations and be licensed by NHRA.
 - 4.1.2. The provision of telehealth services shall only offered through an NHRA licensed telehealth facility or NHRA licensed standalone telehealth platform. Telehealth services shall be physician led.
 - 4.1.3. NHRA licensed Health Facility should have the following in place:

- 4.1.3.1. Comply with NHRA requirements for licensure, timeframes for submission and resubmission of documentation and adhere to any corrective measures issued by NHRA.
- 4.1.3.2. Employ the minimum required number of physicians for the provision of telehealth services as per NHRA Decision 2 for Licensing Health Facilities.
- 4.1.3.3. Provision of adequate supply and qualified human resources to provide telehealth services. Telehealth service management must not compromise staffing requirements essential to provide ongoing healthcare face-to-face in person service(s).
- 4.1.3.4. Facilities must ensure that professionals train, assess and evaluate physicians and administration staff on an ongoing basis on the core competencies required for telehealth services. Training must always be documented and shall include:
- a) Benefits and limitations to telehealth.
 - b) Legal, ethical, and clinical aspects of telehealth.
 - c) Medical liability and the complaints management process.
 - d) Code of conduct of health professionals as per DHA requirements.
 - e) Use of IT and telehealth communication systems and processes.
 - f) Electronic health record keeping.
- 4.1.3.5. Training on the use of telehealth services shall be documented and will include core competencies to ensure quality and patient safety.
- 4.1.3.6. Management must ensure physicians receive ongoing Continuing Professional Development (CPD) in order to ensure physicians, maintain the necessary knowledge and competencies continuous effective, safe and high-quality telehealth services within the remit of their specialization.
- 4.1.3.7. Ensure a written Contract or Memorandum of Understanding (MOU) is in place and kept up to date where telehealth service provision entails two or more entities.

- a) The MOU shall detail out the roles and responsibilities of each party and align with Bahrain Laws and Regulations.
- b) The NHRA licensed health facility shall maintain a record, or all physicians engaged in telehealth services.

4.1.4. The following policies and procedures must be in place:
shall have policies and procedures in place to govern all administrative functions that responsibly include and address aspects of telehealth with regards to:

- Human resource management
- Privacy and confidentiality
- Follow NHRA credentialing requirements
- Fiscal management
- Ownership of patient records
- Documentation
- Patient rights and responsibilities
- Network security
- Telehealth equipment use

- 4.1.4.1. Telehealth service description with scope of services available to members of the public.
- 4.1.4.2. The service description shall fulfil patients' healthcare needs and assure continuity of care.
- 4.1.4.3. Patient identification, selection and risk assessment.
- 4.1.4.4. Patient consent with Arabic and English
- 4.1.4.5. Clinical care pathways and prescribing protocols must include red flags for referral and emergency referral and be reviewed on a periodic basis.
- 4.1.4.6. Amendments to clinical care pathways and prescribing protocols must be documented.
- 4.1.4.7. Health record documentation management.
- 4.1.4.8. Patient privacy and confidentiality.
- 4.1.4.9. Patient referrals follow up and continuity of care.
- 4.1.4.10. Incident recording and reporting.

- 4.1.4.11. Quality and safety improvement.
- 4.1.4.12. Emergency protocol for emergency patient cases.
- 4.1.4.13. Equipment testing, maintenance and failure management.
- 4.1.4.14. Network and data confidentiality, transmission, storage, and access security.
- 4.1.4.15. Grant NHRA access to the program to see the stored calls for reasons of scrutiny or investigation of complaints received.
- 4.1.5. Develop and implement Standard Operating Procedures (SOPs) governing telehealth services.
- 4.1.6. Identify, develop, and ensure compliance with operational policies and procedures essential for effective telehealth service delivery and ensure their periodic review.
- 4.1.7. Health facilities providing telehealth services that establish collaborative partnerships shall be aware of applicable legal and regulatory requirements for appropriate written agreements, memorandum of understanding, or contracts. Those contracts, agreements, etc., shall be based on the scope and application of the telehealth services offered, and, shall address all applicable administrative, clinical, and technical requirements
- 4.1.8. Health facilities shall have infection control policies and procedures in place for the use of telehealth equipment and patient peripherals that comply with NHRA requirements
- 4.1.9. Health facilities providing telehealth services shall have processes in place to ensure the safety and effectiveness of equipment through on-going maintenance.
- 4.1.10. A health facility providing telehealth services shall ensure the following requirements are met:
 - 4.1.10.1. Equipment and devices for distant site use are be compatible in accordance with requirements for technology and technical safety and security in Bahrain.
 - 4.1.10.2. Equipment and devices approved for medical use are in good functioning condition.
 - 4.1.10.3. Equipment maintained in accordance to the manufacturer's specifications to support all applicable telehealth services.

- 4.1.10.4. Availability of integrated technical network with uninterrupted connectivity and adequate bandwidth.
- 4.1.10.5. The technical network must have the capacity to integrate with healthcare provider electronic health records system.
- 4.1.10.6. Provision of uninterrupted/backup power supply.
- 4.1.10.7. Provision of secure servers (including iCloud) with relevant data backup.
- 4.1.10.8. Provision for technical systems to record and document patient information and telehealth services.
- 4.1.10.9. Protection of information stored in the electronic health records.
- 4.1.10.10. Secure, private and soundproof workspaces to safeguard patient privacy and confidentiality and limit access to authorized and responsible staff.
- 4.1.10.11. Patient privacy must include:
- a) Privacy of personal information.
 - b) Privacy of personal communications.
 - c) Privacy of consulting space.
 - d) Privacy of the service fees that taken by the patient.
- 4.1.10.12. Ensure alternative ways of communication between the healthcare service provider and patient are in place.
- 4.1.11. Facility must have in place an electronic health record system that guarantees patient identification, authentication, collection of safe, secure, and comprehensive patient information during the provision of telehealth services, including voice recording in for quality control and quality improvement.
- 4.1.11.1. Ensure consent is obtained from the patient (or their legal guardian) prior to use of telehealth technologies (Consent to access telehealth services may be signed electronically or in person prior to the initiation of telehealth services). The health facility shall obtain and document evidence of patient consent for the use of telehealth services, which shall be embedded within the service workflow and maintained in the patients' health records.
- 4.1.11.2. Develop and implement a systematic quality improvement and performance management process that encompasses quality assurance and quality control.

- 4.1.11.3. Provide an appropriate environment and culture to encourage physicians and administrative staff to report and document incidents.
- a) Develop and implement a process to effectively identify and manage incidents and rectify any issues in an integrated manner, including serious incidents.
 - b) Report all sentinel events and major incidences to the Medical Complaints Section.
- 4.1.11.4. Have in place formal complaint and grievance process to resolve any potential ethical concerns or issues related to provision of telehealth services.
- 4.1.12. Health facilities providing telehealth services should ensure their services are effective, safe and of high quality to meet the needs of patient.
- 4.1.13. Health facilities shall meet required published technical standards for safety and efficacy for devices that interact with patients or are integral to the diagnostic capabilities of the practitioner when and where applicable.
- 4.1.14. Clinical assessment of the patient shall only be undertaken by NHRA licensed physician to ensure current and ongoing needs of the patient are identified, documented and met.
- 4.1.15. Telehealth providers must ensure policy and procedures are in place for emergency requests. The policy and procedures shall include:
- 4.1.15.1. A written protocol appropriate to the telehealth services being provided.
 - a) The protocol should be tested on a regular basis.
 - b) The outcome of the testing and improvement plan should be documented.
 - 4.1.15.2. Service contact number for emergency care and management.
 - 4.1.15.3. Contact number for local emergency services.
- 4.1.16. Offer telehealth services in at least Arabic and English languages. The healthcare provider is encouraged is to make use of

interpretation services to assure patient groups that can benefit from telehealth services are not excluded.

- 4.1.17. Safeguard and preserve patient rights and treat patients with respect and dignity.
- 4.1.18. Assure professionalism and confidentiality during the provision of healthcare services to the patient.
- 4.1.19. Offer open, honest and courteous communication with patients, physicians, healthcare professionals and administrative staff.
- 4.1.20. Include a satisfaction assessment at the end of the teleconsultation.
- 4.1.21. Health facility management and physicians providing telehealth services must ensure complete documentation of information and communication in accordance with the laws and regulations of Bahrain.
- 4.1.22. The physician shall document in the patient's health records each telehealth encounter including but not limited to:
 - 4.1.22.1. The type of telehealth service and technologies used.
 - 4.1.22.2. The name and license number of the healthcare professional(s) involved in the encounter. As Health professionals providing telehealth services shall be fully licensed and registered in NHRA and with respect to the site where the patient is located, administrative, legislative, and regulatory requirements.
 - 4.1.22.3. The date and time and location of the practicing care site and receiving care site.
 - 4.1.22.4. Confidentiality and security of patient information and patient consent.
 - 4.1.22.5. To ensure patient's ongoing care, the health facility providing telehealth services shall make patient's information available to other healthcare professionals during handover, transfer, and discharge.
 - 4.1.22.6. Patient details and the patient's condition including past history, family history, signs and symptoms described by the patient and/or observed by the healthcare professional(s). **Regarding to annex 3**

4.1.22.7. Diagnosis and recommended treatment or therapy / treatment plane provided by the Physician.

4.1.22.8. Health professionals shall be aware of their locus of accountability and any/all requirements (including those for liability insurance) that apply when practicing telehealth in another jurisdiction

4.1.22.9. Health professionals using telehealth shall be cognizant of when a provider-patient relationship has been established within the context of a telemedicine encounter between the health care provider and the patient, whether interactive or store-and-forward, and proceed accordingly with an evidence-based, best possible standard of care.

4.1.22.10. Health professionals providing telehealth services shall have the necessary education, training/orientation, and ongoing continuing education/professional development to ensure they possess the necessary competencies for the safe provision of quality health services in their specialty area.

4.1.23. Accessibility and retention of health records must be consistent with applicable laws and regulations.

4.1.24. Information, communication, and technology data should be maintained for a minimum of **5years** from the date of the last health procedure.

4.1.25. Ensure the following information for the telehealth service(s) are available online for the public:

4.1.25.1. Health facility name, location, contact details, catalogue of services provided, days and hours of operation etc.

4.1.25.2. Appropriate uses and limitations of telehealth services, especially emergency cases.

4.1.25.3. Information on physicians privileged to provide telehealth services, including licensure title, the licensing authority, qualifications, training, experience, specialisation and contact details.

4.1.25.4. Medical conditions that could be treated using the telehealth services.

- 4.1.25.5. Timeframe for responding to enquiries received in writing or by other means of electronic communication.
- 4.1.25.6. Circumstances in which patient health information may be disclosed.
- 4.1.25.7. Rights of patients with respect to patient health information.
- 4.1.25.8. Feedback regarding the site and the quality of information and services.
- 4.1.25.9. Mechanism to register complaints, including information regarding filing a complaint.
- 4.1.25.10. All service fees, payment options and refund Policy.
- 4.1.25.11. Terms and conditions for the service
- 4.1.25.12. Disclosure for any product or service information provided through third party agreements.
- 4.1.25.13. Ensure policies are in place for billing, scheduling, cancellation, and refunds.
- 4.1.26. Facility must comply with patient privacy, consent, confidentiality, protection, and security of data and maintain systems and processes for data collection, storage, and backup of patient health information
- 4.1.26.1. Management must ensure validity and credibility of health data and information by maintaining safety protocols for vandalism, damage, modification, alteration, or unauthorized deletion.
- 4.1.26.2. Management must ensure the availability of health data and information to authorized staff, when needed.
- 4.1.27. Physicians must comply with the scope and rules for prescribing for telehealth services in accordance laws and regulations and the NHRA guidelines for prescribing.
- 4.1.27.1. Physicians must be diligent when prescribing medications and consider frequent prescribing of medications that are addictive, unsafe or deemed unusual in their request or dosage or are contraindicated.
- 4.1.27.2. Limitations to prescribing without confirmatory lab testing shall be explained to the patient.

4.1.27.3. The patient must be made aware of medications groups that cannot be prescribed through telehealth.

4.1.27.4. The patient must be made aware of the risks associated with prescribed medications.

Telemedicine Ethics

Although Telemedicine is not a practice in and of itself, practicing at a distance creates a unique relationship with the patient that requires attention to and adherence to professional ethical principles. A healthcare facilities or health professional that adheres to ethical Telemedicine principles shall:

- 1) incorporate organizational values and ethics statements into the administrative policies and procedures for Telemedicine
- 2) be aware of medical and other professional discipline codes of ethics when using telemedicine.
- 3) inform the patient of their rights and responsibilities when receiving care at a distance (through telemedicine) including the right to refuse to use telemedicine.
- 4) provide patients and providers with a formal process for resolving ethical questions and issues that might arise as a result of a telemedicine encounter.
- 5) eliminate any conflict of interest to influence decisions made about, for, or with patients who receive care via telemedicine.