

DHA Issues New Standard for Telehealth Services

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This article focuses on the recent telehealth standard issued by the Dubai Health Authority ('DHA'), but also provides a summary of the most recent developments regarding telehealth regulations in the United Arab Emirates ('UAE'), and includes reference to the historical legal framework for background and context.

Background

It seems that 2019 has been the year of telehealth for UAE regulators.

This summer, the long awaited executive regulations to the federal medical liability law of 2016 ('Medical Liability Law') were issued, setting out, amongst other things, the terms and conditions for providing telehealth services in the UAE, solidifying at the federal level the permissibility and parameters for providing such services.

For historical context, federal laws concerning the practice of human medicine and the medical liability law of 2008 contained an obligation for a physician to see patients face-to-face and to conduct a physical, in person clinical examination. The Medical Liability Law paved the way for the health authorities in the UAE

to establish a system that would permit the provision of distance health services; however, the law required that such systems developed by the regulators be subject to the terms and conditions set by the executive regulations of the Medical Liability Law. While the executive regulations were issued only this summer, seeing the value in providing a pathway for telehealth, each of the DHA, the Department of Health in Abu Dhabi ('DOH'), and the Dubai Healthcare City Authority - Regulatory ('DHCR') had already issued telehealth regulations in respect of healthcare services provided in their respective jurisdictions.

Telehealth - A Priority for Dubai

In 2017, DHA issued Administrative Decision Number 30 of 2017 to regulate the practice of telehealth services in the Emirate of Dubai (the 2017 regulation has recently been repealed). Since then, Dubai has seen a surge in the provision of telehealth services.

Dubai's 'Fifty-year Charter', declared in 2019 by H. H. Sheikh Mohammed bin Rashid Al Maktoum, Vice President and Prime Minister of the UAE and Ruler of Dubai, lists nine articles to shape the future of Dubai. Article 5 is titled "A Doctor to Every Citizen", stating:

'We aim 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 government 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'.

To fulfil this article, the DHA 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;
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 incentivise the use of telemedicine services; and
7. developing the appropriate legislative framework for the provision of telemedicine services in the Emirate of Dubai.

DHA - 2019 Telehealth Standard

In September 2019, DHA issued the Standards for Telehealth Services ('Standards'). These Standards set out the minimum requirements for the provision of telehealth services, focused on ensuring high quality care delivery and ensuring protection of patient data and confidentiality.

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

The Standard divides telehealth into six key areas:

- teleconsultation;
- telediagnosis;
- telemonitoring (remote patient monitoring);
- mHealth (mobile health);
- telerobotics and robot-assisted services; and
- telepharmacy.

All health facilities or standalone telehealth platforms seeking to provide telehealth service(s) must be licensed by DHA, with specific approval to conduct telehealth. Telehealth service licence categories include:

- adding telehealth services to an existing DHA licensed health facility category;
- standalone telehealth centre;
- telehealth booth at a specific location; or
- telehealth platform.

Specifically excluded from telehealth services are:

- emergency cases where immediate life threatening intervention or referral is required;
- the prescribing of of narcotic, controlled or semi-controlled medication;
- platforms used for face-to-face in person consultation; and
- video recording during patient consultation and storage of patient video files.

The Standard permits providers to obtain an exemption to the video recording prohibition by submitting a written request to record video on an ad hoc or time limited basis for physician education and quality improvement purposes.

Consent to access telehealth services must be obtained and documented for each encounter. Such consents may be signed electronically or in person, prior to the initiation of telehealth services.

Telehealth services must be physician led and DHA licensed physicians, nurses, and allied health professionals must be privileged in accordance with DHA regulations to provide telehealth services.

Data, Privacy & Telehealth Devices

The Standard echoes that when it comes to data transmission and storage, compliance is required with Federal Law No. 2 of 2019 Concerning the Use of the Information and Communication Technology in the Area of Health ('ICT Health Law') (For a further discussion regarding this resolution, see our November 2019 Law Update article entitled "[Significant Development In UAE's Medical Liability Law](#)"). The 2019 theme of data localisation in the UAE is repeated in the 18 months from the date of issuance of the Standard or licensure, whichever is later, from an internationally recognised accreditation body for telehealth services.

The Standard highlights that certain telehealth equipment will need to be approved by the Telecommunications Regulatory Authority ('TRA'). In all cases, any devices used in the provision of telehealth must be evaluated to ensure compliance with the applicable authorities and regulations, such as the Ministry of Health & Prevention ('MOHAP') for medical devices, and DHA for medical display screens, for example.

Artificial Intelligence

In terms of the use of artificial intelligence ('AI'), the DHA requires that a 'responsible' physician is appointed for any medical errors resulting from AI technology. It is not clear whether this physician will have personal medical liability for such AI medical errors, or merely will act as the individual responsible for receiving reports of such errors and implementing remedial actions.

Telehealth Booth

A telehealth booth must seek approval from the DHA at least two weeks prior to the allocation or relocation of the telehealth booth. It is required that the booth includes a waiting area, as per the minimum requirements for a healthcare clinic, in addition to allowing for patient privacy during the provision of telehealth services.

Telehealth booths will not be permitted to be self-sufficient. At least one registered nurse ('RN') must be present at the booth during operating hours and there must be at least one accountable DHA licensed physician responsible for the services provided at the booth.

Telemonitoring & Patient Remote Monitoring

Telemonitoring and patient remote monitoring ('PRM') may be provided after an in person assessment in the healthcare facility or through a teleconsultation. PRM providers are required to only procure and provide ICT technologies that comply with TRA requirements, the ICT Health Law, and DHA interoperability standards. Contracts and memoranda of understanding are to be in place where support services are used.

Physicians offering PRM services must ensure that patients are made aware of and consent to the use of monitoring devices that collect information related to patient location or other non-health patient data.

PRM service providers must ensure that there is in place a written policy for data collection, use and storage, including that such data be reliable, valid, accurate and timely, and form part of the electronic health record.

mHealth

mHealth devices must comply with the requirements set out by the UAE's National Electronic Security Authority ('NESA'), TRA, the ICT Health Law, and MOHAP regulation for the use of medical devices. Further, DHA sets out certain other requirements for mobile medical applications, including that such applications must be submitted for DHA review and approval.

Telerobotics & Robot Assisted Services

Certified compliance for use of medical devices for telesurgery is required with the United States Food and Drug Administration's Quality System Regulation, or the European Union's CE Marking, and ISO 9001 and

ISO 9002 Standards.

Physicians must be trained on telesurgery, to include competencies for force (haptic) feedback, time delay, and depth perception management systems.

The mechanical design classification of robots and robotic systems must be suitable for the type of telesurgery being undertaken. Medical equipment and devices appropriate for the type of telesurgery (general, thoracic, cardiac, gastrointestinal and colorectal, gynaecology/echography and ultrasonography, urological, neurosurgery, spinal, ophthalmology, and ear neck and throat) must be used, to include robot assisted arm (and arm cart).

Telepharmacy and Vending Machines

Telepharmacy service providers must have in place an electronic pharmacy system to manage transaction information and track movement of medications. Controlled, semicontrolled, and narcotic medication are not permitted to be prescribed or dispensed through telehealth services. Prescriptions must be issued through an online prescription system that includes the electronic transfer of the prescription to the pharmacist by the treating physician or the prescription being uploaded online by the patient. The teledispensing pharmacy must be licensed by DHA to operate as a pharmacy as well as carry out tele-dispensing. Patients may access tele-dispensing services for:

- prescription only medicines ('POM');
- over the counter ('OTC') medicines;
- nutrition and supplements;
- herbal medications;
- skin and hair care products;
- baby and mother care products;
- personal care, foot care and eye care;
- beauty supplements and accessories;
- medical equipment;
- rehabilitation products;
- first aid; and
- orthopedic support products.

Medication vending machines must be approved by the MOHAP and may provide OTC and general sale list products. If the vending machine is located near and affiliated with a DHA licensed pharmacy, pharmacy only medicine and POMs may be dispensed. 2019 has been the year of telehealth for UAE regulators

Conclusion

Telehealth providers are required to report to DHA on specific key performance indicators each quarter. Backed by the ruler of Dubai, we envision that the DHA will use these reports to closely monitor telehealth providers and continue to examine the scope of telehealth services, the uses thereof, and the future of telehealth in the UAE. This Standard provides significant amounts of clarity and welcomed new elements to telehealth in Dubai.

healthcare sector. For further information, please contact healthcare@tamimi.com.