United Arab Emirates – In Case You Missed It: Key Dubai Healthcare Regulatory Developments of 2021

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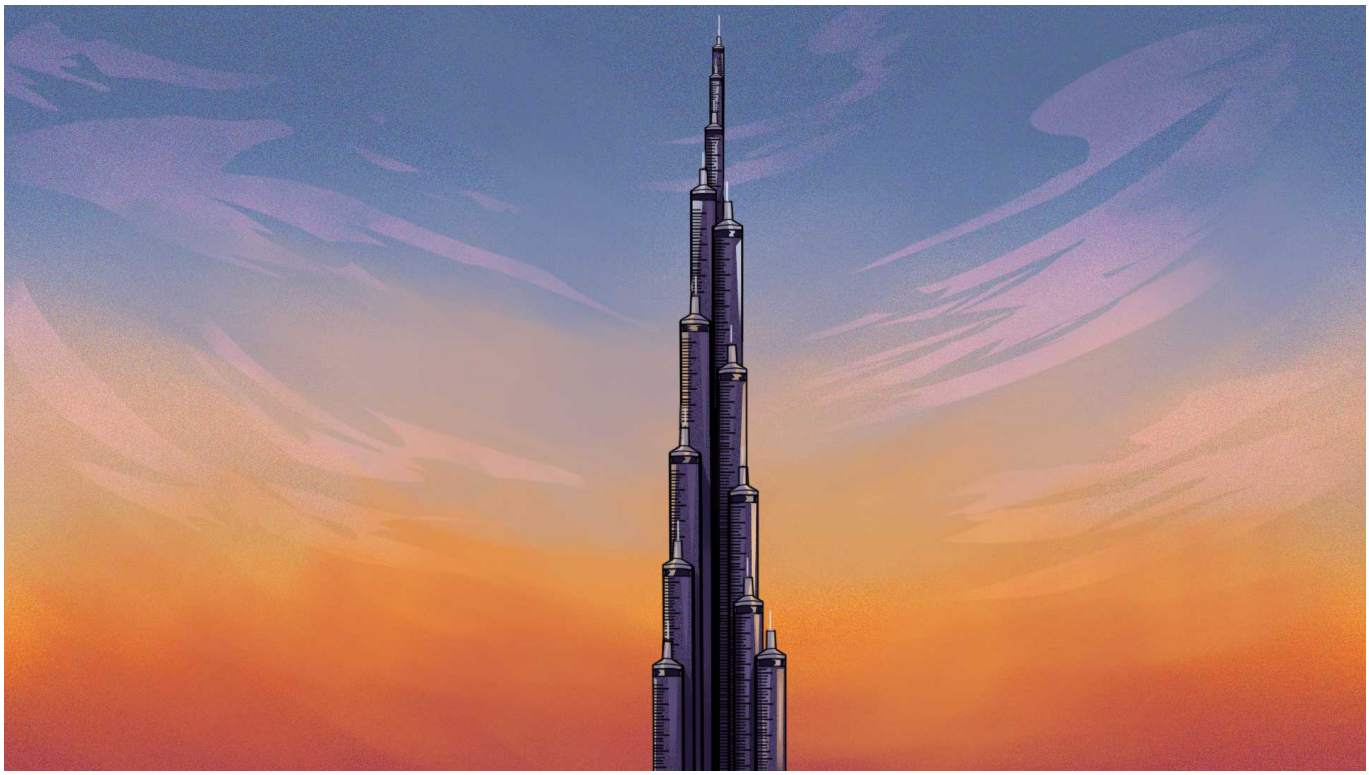

This illustration is inspired by the Burj Khalifa in Dubai, United Arab Emirates.

As if handling the pandemic and managing public health was not enough, the Dubai Health Authority ('**DHA**') in the Emirate of Dubai, United Arab Emirates, issued a deluge of new regulations thus far in 2021. In this article, we set out by brief summary the key updates and new legislation issued by the DHA through October 2021.

Telehealth Policy – new document

This policy sets out the regulatory requirements for licensure of telehealth services. Telehealth services are divided into six key areas: 1) teleconsultation; 2) telediagnosis; 3) telemonitoring (remote patient monitoring); 4) mHealth (mobile health); 5) telerobotics and robot-assisted services; and 6) telepharmacy. All telehealth services and telehealth platforms operating in Dubai must be licensed by DHA. Telehealth services are licensed under one of the following areas: 1) call centre; 2) telebooth; or 3) add-on services. It is not permitted to store, develop, or transfer data and health information outside the country that is related to health services provided within the country, except in limited cases.

In addition, compliance is required with, amongst others: federal laws regarding telehealth services, the use of the information and communication technology ('**ICT'**) in healthcare, and medical liability; the

National Electronic Security Authority Standards and Guidelines for Cyber Security; the Telecommunications and Digital Government Regulatory Authority for Voice Over Internet Protocol channel requirements related to telehealth; the Dubai Health Insurance Corporation requirements for telehealth approval processes e-claims, reimbursement, and documentation; and applicable DHA standards.

Standards for Telehealth Services – new version

Version 3 issued several updates, including requiring all facilities providing telehealth services, as well as all telehealth platforms intended for internal or commercial use, to obtain approval from the DHA prior to providing such services. Also included are updates to: the exceptions to store, develop, or transfer data and health information outside the country; requirements for electronic consent; and certain subsections related to telepharmacy.

Guidelines for Reporting Telehealth Key Performance Indicators – new version

All telehealth service providers are required to adhere to the quarterly collection and reporting of performance indicators within the two-week deadline, as specified in the new version 2 of the guideline. Amongst other updates, the new version has added reporting deadlines and a new KPI on the percentage of telehealth calls from outside Dubai.

Telehealth Clinical Guidelines – new documents

DHA issued a variety of clinical guidelines pertaining to managing a variety of symptoms through telehealth. The guidelines are presented in a format comprising of clinical history/symptoms, differential diagnosis, investigations, and management.

Clinical Trials Policy – new document

This policy regulates the conditions and requirements for conducting clinical trials in DHA licensed health facilities. All DHA licensed health facilities seeking to conduct clinical trials shall obtain approval from the Medical Education and Research Department and ethical approval from the Dubai Scientific Research Ethics Committee. Clinical studies/trials may only be carried out in the following facility categories: 1) outpatient care setting; 2) inpatient care setting; and 3) clinical laboratories. All studies must comply with good clinical practice principles as set out by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.

Hospital Accreditation Policy – new document

All DHA licensed hospitals are required to be accredited by an International Society for Quality in Healthcare (ISQua) International Accreditation Programme approved accreditor within 24 months from the point of licence activation. Hospitals should fulfil the standards for operation as a hospital including, but not limited to, outpatient, inpatient services, operating theatre, and pharmacy. In addition to hospital accreditation, accreditation for other specific units, services, and/or specialised services is required – such as laboratory services – stipulated in other policies, standards or circulars issued from DHA. Evidence of maintaining accreditation must be submitted annually during facility licensure through the online Sheryan

licensing system.

Role and Responsibilities of Medical Director Policy – new document

All DHA licensed healthcare facilities must have in place a medical director who is a DHA licensed healthcare professional having responsibility and oversight over the medical services within the DHA licensed health facility. The medical director is responsible for medical ethics, having a leadership role, participating in the facility's governance, ensuring quality and safety, supporting medical education and training, and ensuring that the facility complies with all federal and local laws and regulations. Upon licensure of the facility, all medical directors will be required to sign an undertaking to comply with this policy.

Standards for Standalone Day Surgery Centres – new version

Version 3.1 updates various elements of the standard, including amongst others: requirements for informed consent (patients undergoing elective surgery must provide their consent at the pre-op assessment and on the day of surgery); restricting the permitted hours to administer anesthesia for Class CM (deep sedation/analgesia) and Class C (general anesthesia) facilities to before 3:00 PM; requiring that the consultants and specialists leading day surgery centres must have a minimum of 10 years experience in surgery; clarifying clinical categories for operation as per the sedation level; adding the requirement that ambulatory care pharmacy services require a full-time pharmacist; and updating the medication list for Class B (moderate sedation/analgesia – conscious sedation) and Class CM facilities.

Guidelines for Reporting Standalone Day Surgery Centre Key Performance Indicators – new document

The DHA Standards for Standalone Day Surgery Centres requires day surgery centres ('**DSC**') to report a set of 14 key performance indicators ('**KPI**'). This document provides guidance regarding reporting on these KPIs and includes a description of each KPI. Providers are expected to report the KPIs on a quarterly basis using the provided KPI submission tool.

Standards for Hyperbaric Oxygen Therapy ('HBOT') Services – new version

Version 2 added a clearer definition of informed consent, inside attendant, and legal guardian, as well as the additions of policies for management of paediatric patients, management of critically ill patients, and management of patients with known infections. The standard elaborates on healthcare professional requirements, the management of HBOT during a pandemic, and the staffing matrix, amongst others additions.

Standards for Interventional Cardiology Services – new document

DHA licensed health facilities opting to add interventional cardiology services to an existing hospital licence are required to, amongst others: 1) apply for permission to add the service to the existing health facility licence; 2) meet the facility design requirements as per DHA Health Facility Guidelines (HFG), 2019, Part B – Health Facility Briefing and Design, 40 – Cardiac Investigations Unit; and 3) be accredited by an

internationally recognised accreditor for interventional cardiology services.

Standards For Autologous Haematopoietic Stem Cell Transplantation – new document

DHA licensed health facilities and professionals providing Autologous Haematopoietic Stem Cell Transplantation ('**AHSCT**') services must apply for inspection and licensure and the transplant unit must be led by a Clinical Program Director who has the necessary experience and competencies to supervise the day-to-day operations of the service. AHSCT services may only be performed in a hospital setting that fulfils the requirements set out in the standard. Institutions providing AHSCT treatment should be affiliated with a clinical trial approved by the DHA Ethics Committee 12-18 months from service commencement. The service must achieve and comply with FACT – JACIE International Standards for Cellular Therapy, Product Collection, Processing and Administration, Storage and Collection accreditation 24 months from licensure activation. The standard is limited to autologous (same person) treatment with predetermined inclusion and exclusion criteria.

Standards for Medical Advertisement Content on Social Media – new document

This standard sets out the requirements for managing medical advertisement content on social media for DHA licensed health facilities and healthcare professionals. This standard does not detail specific scenarios, but rather sets out the parameters for good social media advertising practice. The official account of the health facility must state the corresponding medical advertisement licence number provided by Ministry of Health and Prevention ('**MOHAP**'). If the healthcare professional is a visiting doctor or working in other countries in addition to Dubai, his/her social media account for Dubai must be separated and must comply with this standard.

Pharmacy Guidelines – new document

The guideline seeks to support pharmacies to comply with federal and local regulations concerning pharmaceutical practice. Covered in the guideline are priority areas, including: good pharmacy and vigilance practice; code of ethics for pharmacist; prescribing and dispensing medication; and record management and patient confidentiality. The minimum requirements set out in the guideline apply to any DHA licensed healthcare professional and DHA licensed health facilities, including, but not limited to, pharmacies, general or specialised hospitals, day surgical centres, fertility centres and outpatient facilities dealing with medications and pharmaceutics in Dubai, and includes storage, distribution, prescribing, dispensing, preparation, administering, and/or handling drugs.

Dubai Dental Clinical Protocols – new documents

DHA issued Dubai Dental Clinical Protocol (2021), which includes a number of clinical guidelines pertaining to dental practices in Dubai, including: restorative dentistry, endodontics, periodontics, oral and maxillofacial surgery, prosthodontics, implant dentistry, paediatric dentistry, orthodontics, community based dentistry, infection control, and dental radiology. It is obligatory to use the consent forms attached to the respective guidelines. A variety of workshop were heldto introduced these guidelines and answer any related queries.

Onboarding Hospitals to the Health Information Exchange Platform (NABIDH)

All hospitals operating within the jurisdiction the DHA must ensure that they are onboard to the NABIDH platform as a pre-requisite to applying for a new or renewed hospital licence, effective 31/12/2021. All hospitals should have an electronic medical record ('**EMR**') that complies with the NABIDH Minimum Data Set and standards. Hospitals have the right to choose any EMR in the market that complies with NABIDH requirements.

Policy on Artificial Intelligence in the Healthcare – new document

All artificial intelligence ('**AI**') solutions for healthcare must conform to international, UAE federal, and Emirate of Dubai information laws, regulations, and guidelines with respect to human values, patient autonomy, people rights, and acceptable ethics. The policy applies to: a) all healthcare facilities and professionals licensed by DHA utilising AI in healthcare services; b) national and locally based international AI developers that utilise Dubai based population or patient clinical and nonclinical data to develop AI solutions; c) UAE based pharmaceutical manufacturers, health insurers, public health entities utilising AI solutions for healthcare services in Dubai; d) all AI solutions used by healthcare researchers involved in human research in Dubai.

Brain Death Determination Policy – new version

In collaboration with the National Committee for Human Organ & Tissue Transplants, DHA issued version 3 of the Brain Death Determination Policy to ensure the diagnosis of brain death has been carried out as per worldwide standards and international best practices.

Healthcare Data Quality Policy – new document

The policy is intended to cover all patient information that is recorded within the healthcare facility. The principle emphasis of the policy is on electronic medical records ('**EMR**'), the documents used to populate those electronic systems, and the data extracted from them. The policy must be followed by all healthcare facility staff involved in the collection, recording, storage, processing, or use of patient-related data, regardless of their role within the healthcare facility. All digital solutions that manage medical records/patient administrative data (e.g. EMRs, revenue cycle management) must be certified by DHA to ensure that it has the required functionality and security. Patient data covers anything that relates to health interventions, including administrative information, demographic data, diagnosis, treatment, prescribed medication, laboratory tests, physiologic monitoring data, hospitalisation, insurance, etc.

Patient Referral and Inter-Facility Transfer Policy – new version

All health facilities must have in place a system for patient referral and inter-facility transfer in line with the functional scope of the health facility. All DRG guidelines and rules are applicable. The policy applies to patient referrals between health facilities under DHA jurisdiction and inter-facility patient transfers between health facilities under DHA jurisdiction.

Health Facility and Healthcare Professional Audit and Inspection – new version

The new version provides updates to the audit and inspection proesses and obligations for DHA licensed healthcare facilities and healthcare professionals, including the associated ethical and technical violations and administrative violations.

Healthcare Accreditors – new document

The new policy requires that healthcare accreditors are approved and licensed by DHA in order to accredit the provision of healthcare services in the Emirate of Dubai. Amongst others, healthcare accreditors must have legal representation in UAE, with a relevant commercial/trade license issued by the competent authority in Dubai. The approved accreditors will also need to comply with UAE laws, including ensuring that all health data and information stored by the entity complies with the Federal Law No. 2. for the year 2019 on the Use of Information and Communications Technology, and its implementing regulations. (see our articles on this subject here; and also here, and also here). Accreditation for training programs are excluded from the scope of the policy.

The Dubai Healthcare City Becomes Regulated by the Dubai Health Authority

The regulatory purview of the Dubai Healthcare City ('**DHCC**') has been transferred to the DHA, as of 24 October 2021, whereby the DHA replaces the Dubai Healthcare City Authority as regards health regulation responsibilities and competencies, including, but not limited to licensing of healthcare professionals and healthcare facilities in the DHCC, supervising and inspecting healthcare professionals and facilities in the DHCC, and managing patient complaints in relation to DHCC healthcare professionals and facilities. Healthcare facilities and healthcare professionals in the DHCC should now use the DHA's Sheryan online system for licensing. Already existing DHCC facilities should be automatically migrated from the DHCC Massar System to the DHA Sheryan system. All new DHCC healthcare facilities and professionals should use the Sheryan system from the beginning. Facilities that have obtained an initial approval from DHCC for a new healthcare facility will need to re-register with the DHA.

We do not expect legislation developments to slow down anytime soon. Stay tuned for more updates.

Our Healthcare & Life Sciences sector group regularly advise on these types of matters. For further information, please contact healthcare@tamimi.com.