In case you missed it: Key UAE healthcare laws and regulatory developments of 2020

- Associate
- Abu Dhabi

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In 2020 the healthcare sector has been hit very hard by the arrival of the COVID-19 pandemic. The health regulators have issued numerous instructions to public and private sector operators on the handling of the situation. A number of these measures are discussed in this article, but this is not an exhaustive account of the collective effort to fight COVID-19. Further, we have highlighted a quick summary of the new laws and regulations which we have been monitoring. Many of these will require healthcare facilities to update their internal policies to reflect the provisions of the law or regulation.

1. COVID-19 related regulations and guidelines

The National Guidelines for Cinical Management and Treatment of COVID-19

These guidelines were issued by the UAE Ministry of Health and Prevention ('MOH') to provide a protocol on the practical steps to deal with COVID-19 cases as follows:

1. detail the measures necessary to protect hospital staff, patients, and visitors; and
2. outline the prognostic factors and markers for a severe COVID-19 disease, detailing the medications that may be prescribed and their possible side

These guidelines are not intended to override the clinical decisions that will be made by clinicians providing individualised patient care.

DOH Circular No. 46 of 2020 on COVID-19 Research and Clinical Trials

This Circular was issued by the Department of Health Abu Dhabi ('DOH') for the sake of the safety of patients participating in medical research and clinical trials in general and, in particular, in research related to COVID-19 treatment. The DOH requires that all health facilities adhere to the following;

1. prevent overlaps of clinical trials to ensure patients' safety;
2. under no circumstance should patients enroll or participate in more than one clinical trial simultaneously, unless there is a clear protocol for compassionate use outlined in the original clinical trial proposal;
3. all Principal Investigators ('PIs') and clinical trials' staff must strictly adhere to documentation of events on patients' files;
4. in order to enhance clinical trials monitoring at DOH level, all PIs must submit clinical outcomes (recovery, no change, death, and adverse events) during the course of approved clinical trials to DOH;
5. all clinical trials involving the use of immunomodulators and drug therapies must be carefully reviewed, monitored, and documented;
6. mortality and data review on an ongoing basis for all COVID-19 related deaths must be kept;
7. DOH will conduct further investigations and reviews to determine causality

DOH Circular No.12 of 2020, Permitting Health Care Professional Rotation between AUH Facilities

To further help fight COVID-19, the DOH issued this Circular that allows all DOH licensed health professionals to work and move between DOH licensed health facilities as deemed necessary, regardless of the facility to which the professional is licensed. This is

in line with a ministerial resolution issued to this effect and is valid until December 2020. A documented agreement between both healthcare providers is required, which must be non-profit and free of charge.

DOH Circular No.10 of 2020, on the Activation of Tele-medicine Services and Medicines Delivery to Homes in Abu Dhabi

This Circular was originally implemented in March 2020 and has been extended each month, with the latest circular extending it until 23 October 2020. It permits healthcare providers to temporarily provide tele medicine services without a permanent telehealth licence from the DOH. Following the conclusion of the Circular's validity, a permanent licence will be required, as per the DOH Telemedicine Standard.

DOH Circular No. 106 of 2020, Extending Medical Home Visits for High Risk Patients

Where the original circular was issued in April 2020, this Circular provides for the extension, until the end of the year, of medical home visits for coronavirus high risk categories under all health insurance policies and schemes where telemedicine services cannot be provided. High risk categories include those over 60 years old and those with underlying medical conditions.

DHA Circular No 1176 of 2020, Permitting The Movement of Health Care Professionals Between Facilities In Dubai

Similar to the DOH Circular No.12 of 2020, the Dubai Health Authority ('DHA') issued this Circular to allow all DHA licensed health professionals to work and move between DHA licensed health facilities as deemed necessary, regardless of the facility with which the professional is licensed. In case of a medical complaint or malpractice, the medical liability lies between the professional and the facilities where the medical services have been offered. Moving between health facilities should be based on a written agreement between the relevant health facilities and professionals. This circular is in effect until cancelled by the DHA.

2.General

Further, to the above mentioned COVID-19 related regulations and guidelines, there have been interesting developments in other areas of healthcare as follows:

DOH Standard on Delivery of Medications

In February 2020, the DOH issued this Standard to outline the requirements that must be fulfilled when a DOH licensed outpatient pharmacy provides a delivery system for over the counter, pharmacy only, and prescription only medicines to their patients. It sets outs the obligations of the pharmacy in assuring the security and safety of delivery systems and ensures compliance with legal and regulatory requirements.

It lists the practical steps that must be performed by the representative of the pharmacy (delivery driver) to assure the security and safety of delivery systems. The Standard outlines that the delivery service may not include narcotics or controlled or semi- controlled drugs.

Abu Dhabi Standard on Healthcare Data Privacy

The DOH issued a new policy on patient healthcare data privacy in September 2020 ('Data Privacy Standard'). The Data Privacy Standard addresses identifiable patient health information, also known as protected health information ('PHI'), setting the minimum data protection requirements including:

- circumstances in which PHI may be used or disclosed;
- secure and optimal use of PHI;
- operational policies, standards, and practices; and
- security and safety of PHI to maintain confidentiality, integrity, availability, and privacy.

The Standard applies to all categories of healthcare entities regulated by the DOH in the Emirate of Abu Dhabi, as well as healthcare professionals, insurance providers, service providers, vendors, brokers, and third- party administrators who have access to and are processing or storing PHI related to Abu Dhabi patients.

Entities are required to have a privacy policy and procedures in place that describe the way they collect, use, and disclose PHI, including guidelines on data collection, processing,

security, localisation, and retention. Further, entities must communicate with relevant health authorities within 24 hours of initial knowledge of a data breach, and implement an incident response management plan and investigate the incident.

This standard comes in line with a number of regulatory developments in Abu Dhabi over the past couple of years in relation to technology and health information privacy and security. (See The Federal Law regulating the Use of Information and Communication Technology in the UAE Healthcare Sector at https://www.tamimi.com/law-update-articles/ the-federal-law-regulating-the-use-of-

information-and-communication-technology- in-the-uae-healthcare-sector/, The DoH Audit Program regarding Abu Dhabi Healthcare Information and Cyber Security Standards at https://www.tamimi.com/news/the-doh-audit- program-regarding-abu-dhabi-healthcare-

information-and-cyber-security-standards/, A Healthy Start to AI Regulation at https:// www.tamimi.com/law-update-articles/a- healthy-start-to-ai-regulation/, and Malaffi EMR Integration Required for All Abu Dhabi Healthcare Facilities https://www.tamimi.com/ news/malaffi-emr-integration-required-for- all-abu-dhabi-healthcare-facilities/.)

Cabinet Resolution No. 29 of 2020 concerning Private Health Facilities

The Resolution issued on 15 April 2020 has been eagerly awaited as it provides the necessary detail to implement the provisions of Federal Law No. 4 of 2015 concerning Private Health Facilities (the 'Law'). The Law is applicable to all private health facilities in the UAE, including those operating in free zones.

The key provisions of the Law include:

1. the requirements for obtaining a licence for the operation or management of a private health facility in the UAE;
2. obligations in relation to insurance contracts, patient rights, qualifications health and safety conditions, pricing, emergency plans, etc.; and
3. a framework for inspections, sanctions and penalties in case of non-compliance

The issuance of the Resolution provides much needed clarity regarding the implementation of the Law. The Resolution helpfully clarifies the requirements for a licence to be issued and provides clarification regarding the management of the facility, depending on its classification (Article 9). Further, Article 7 of the Resolution sets out the necessary procedures and conditions in the event of a death of a private health facility owner. If the owner or a partner of the private health facility passes away, the ownership of or the stake in the same shall devolve upon the legal heirs within six months from the date of passing, based on

a written application to be submitted by the heirs or their legal representative to the competent health authority.

Cabinet Resolution No 6. of 2020 concerning Cord Blood and Stem cells

The Resolution includes the rules and standards to be applied during the granting, collection, testing, processing, preservation, storage, distribution, import, export, and implementation of procedures related to cord blood and stem cells, and other nuclei cells derived from blood-forming cells, such as the bone marrow, peripheral blood, and cord blood.

This Resolution applies to all government and private health facilities at the country level that perform any of the activities covered by the scope of application and are responsible for any of these activities. These facilities are called, within the scope of application of this Resolution, 'Cord Blood and Stem Cells Storage Centres'. Cord Blood Storage Centres may be affiliated with a health facility or be an independent health facility specialising only in this area.

The Resolution provides that all facilities engaged in activities related to the use of primary human cells and stem cells must obtain a licence from the health authority within their jurisdiction (such as the DOH, DHA, Ministry of Health & Prevention, or the Dubai Healthcare City).

The licensed applicant must provide a bank guarantee of AED 10 million (approximately US$2.7 million), and in the event of a violation committed by the licensed facility, an amount commensurate with the nature of the violation committed shall be deducted from the guarantee, provided that the amount deducted due to the violation is returned to the bank guarantee balance by the licensed facility within two months from the date of the deduction.

Federal Law No. 8 of 2019 on Medical Products, Pharmacy Profession, and Pharmaceutical Establishments

The Law was a significant development in the healthcare market in the UAE during January 2020. This Law replaces Law No. 4 of 1983 on the Pharmacy Professional and Pharmaceutical Establishments and Law No. 20 of 1995 on the Drugs and Products. The Law seeks to establish a modern legal framework under which medical and health focused consumer goods are placed into the UAE marketplace.

Under the Law, a number of new requirements are set out in respect of licensing, pricing, post market surveillance, safety, clinical trials, and product registrations. One of the key takeaways is that a marketing authorisation holder must appoint one pharmaceutical establishment as an importer. However, it is noteworthy that the marketing authorisation holder is now able to appoint more than one distributor of the products in the UAE. Historically, import and distribution were carried out in the UAE by one registered agent or distributor.

Marketing authorisation and marketing authorisation holder are clearly defined terms under the Law. The marketing authorisation holder must be registered with the MOH and must adhere to the specific compliance obligations under Articles 3 to 12 of the Law. This includes designating a medical warehouse to import and distribute its products, and agreeing on a strict protocol with the MOH in relation to monitoring the products being sold in the UAE and reporting any incidents or side effects of usage. Medical product establishments in the UAE must be owned by a UAE National in accordance with Article 85 of the Law. The marketing authorisation holder must appoint one or more qualified persons residing in the UAE. The qualified persons must have medical or pharmaceutical qualifications and be licensed in the UAE. They will be jointly liable with the marketing authorisation holder in respect of compliance with the law. This is a shift in direction from the appointed local agent to direct accountability for pharmaceutical companies.

The MOH shall set up a supreme committee for clinical study ethics, which shall be responsible for medical ethics policies nationally. It is noteworthy that the Law has discarded the concept of a scientific office, which existed under the old law. The qualified persons appointed by the marketing authorisation holder is

now responsible for providing scientific and pharmaceutical information to medical establishments in relation to the products and informing of any changes to the compounds of the products. A marketing office may be established in order to promote medical products and fulfil any MOH reporting obligations.

Additionally, there is now a prohibition on the pharmacist being able to substitute or replace prescribed pharmaceuticals, unless the relevant medical professional who issued the prescription is consulted. Breaches of the Law may result in fines for medical establishments of between 1,000 AED and 1,000,000 AED and or suspension, termination, or variation of its business licence. Imprisonment is also a possibility of between six months and five years, depending on the nature of the breach of this Law or repeated offences by an infringer.

DOH Telemedicine Standard

The DOH issued a new comprehensive telemedicine standard (the 'DOH Standard') on 16 September 2020, which governs telemedicine in Abu Dhabi. The DOH Standard permits telemedicine to be provided by healthcare physicians outside of the UAE and allows for specific tele-counselling collaborative partnerships to be entered into with DOH licensed healthcare facilities. The DOH Standard also permits physicians located outside the UAE to perform 'Tele- Medical Interventions', which are defined by the standard as "any interventive medical procedure that is taken remotely via information and telecommunication technologies". In accordance with section 10 of the DOH Standard, a physician based outside the UAE can enter into specific Tele-Medical Intervention collaborative partnerships with DOH tele-medical licensed healthcare facilities.

DHA General Circular No.9 of 2020, on Teleconsultation DSL Codes

The DHA issued an insurance circular establishing five new Dubai Service List ('DSL') codes for billing purposes to cater to teleconsultation services, with effect from 5 April 2020. The codes included those for teleconsultation with a general practitioner, specialist, consultant, allied health provider, and psychotherapy (psychologist), however, it does not include nursing consultations.

All categories of general practitioners, specialists, and consultants conducting teleconsultations will be covered in the respective codes. All service providers, insurers, and third party administrators are encouraged to begin discussions on pricing immediately. As per Policy Directive No. 2 of 2020, all payers must encourage and accept any claims, regardless of whether they had previously not agreed to telehealth services from the same network providers. To clarify, the directive does not mandate the default inclusion of any telehealth providers licensed by DHA that are not part of a payers' network; rather, the directive applies to those network providers with whom the payer has not extended telehealth services previously, which should now be included. The objective is to reduce unnecessary patient visits to medical facilities, where possible, during the COVID-19 pandemic.

Conclusion

Over the past few years, the healthcare sector in the Middle East has witnessed a rapid and significant overhaul of its regulatory frameworks as governments in the region issued new or enhanced laws and regulations, increased enforcement, and implemented programmes to attract private sector investment. This year has been no exception and, in some cases, has even been escalated by the COVID-19 pandemic.

Stay tuned; we expect 2021 to be an equally active year as the dust hopefully starts to settle from 2020.

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