

In Case You Missed It: Key UAE Healthcare Laws and Regulatory Developments of 2019

Christina Sochacki - Senior Counsel - Corporate / Mergers and Acquisitions
c.sochacki@tamimi.com - Jeddah



It is generally considered that healthcare laws and regulations in the Middle East are, on the whole, underdeveloped. In recent years, we have witnessed a dramatic shift, with regional governments adding healthcare as one of the top priorities for reform.

The UAE, in particular the Dubai Health Authority ('DHA'), has made significant strides in 2019. Herein, we highlight by quick summary the new laws and regulations on which we have been monitoring the pulse. Many of these will require healthcare facilities to update their internal policies to reflect the provisions of the law or regulation.

Federal 'Positive List' for Foreign Direct Investment - 2019

Pursuant to the Federal Decree Law No. 19 of 2018 ('Foreign Direct Investment Decree'), a 'Positive List' was released in July 2019 permitting 100 percent foreign ownership in the UAE mainland for various

activities, including: 'medical and dental clinics'; 'hospital activities'; 'veterinary activities'; 'research and development in the scientific field'; and other 'health related activities', under certain conditions.

Our Client Alert on this topic, entitled "[Healthcare – UAE Foreign Direct Investment Developments](#)" can be found on the Al Tamimi & Company website under the [News](#) section.

Federal Law No. 5 of 2019 Regulating the Practice of the Medical Profession

This law repeals and replaces Federal Law No. 7 of 1975 on the Practice of the Medical Profession and offers a refresh to a dated law.

As echoed in other pieces of legislation, it remains that: no person may conduct medical practices in the UAE without a licence from one of the applicable health authorities; no physician may sell medicines or medicine samples to patients nor advertise specific medicines or direct patients to buy medicines from a certain pharmacy; and it is prohibited for a physician to receive a percentage from the income of any pharmacy, laboratory, another physician or another facility for referring a patient thereto to benefit from their services or to receive any financial or inkind consideration in this regard.

A number of points critical to implementing the law are left to the executive regulations, which have not yet been issued but are expected within the coming months.

Federal Law No. 2 of 2019 Concerning the Use of the Information and Communication Technology in the Area of Health

The ICT Health Law applies to all methods and uses of information and communication technology ('ICT') in the UAE healthcare sector, including in free zones. The ICT Health Law expressly prohibits the processing, generating, transferring, or storing of medical records and health information outside the UAE, in relation to health services carried out in the UAE, except where a resolution to do so has been passed by the relevant authorities.

The ICT Health Law is to be supplemented by executive regulations, which are expected to provide clarity on many of the open queries concerning the data localisation requirements under this law.

We further discuss this law in our November 2019 Law Update entitled "[The Federal Law regulating the Use of Information and Communication Technology in the UAE Healthcare Sector](#)".

Federal Cabinet Resolution No. 40 of 2019 - Regarding Federal Law Decree No. 4 of 2016 Concerning Medical

Liability

The Resolution provides necessary additional details to implement the provisions of the Medical Liability Law (Federal Law Decree No. 4 of 2016 concerning medical liability). Of key importance is that the Resolution includes the long awaiting definition for 'gross' medical errors.

The Resolution also sets out the terms and conditions for the provision of remote health services, solidifying at the federal level the permissibility and parameters for providing telehealth services in the UAE.

We further discuss this resolution in our November 2019 Law Update article entitled "[Significant Developments: UAE Medical Liability Law](#)".

DHCC Teleconsultation Policy - 2019

The Dubai Healthcare City Authority ('DHCA') issued a policy, which supplements DHCA's Standard for Telehealth Services, to govern 'remote telecommunications, generally for the purpose of diagnosis or treatment and may include services enabled by a range of secured telecommunications media such as, telephone, internet based video, email and other similar electronic-based communications provided by a DHCA Licensed Service Provider'. The policy applies to both physician-to-physician and patient-to-physician consultations, for 'current and established patient populations'.

The prescription of medications, including over the counter, as a result of a teleconsultation visit is limited to DHCA licensed healthcare professional with prescribing privileges.

DHCC Tele-radiology Policy - 2019

The DHCA issued a policy to govern 'the electronic transmission of diagnostic radiological images in digital form between locations for diagnosis and reporting by a clinical radiologist'. The policy also applies to both physician-to-physician and patient-to-physician consultations.

All healthcare professionals utilising teleradiology platforms must be licensed by DHCA as radiology specialists. Patient consent must be obtained before any transfer of data is initiated and such data transfers must be in compliance with the ICT Health Law.

The same DHCA licensed healthcare professional should interpret the examination and issue the report to the referring clinician, and results must be communicated and integrated into the base hospital's radiology information system or an external system such as, picture archiving and communications system ('PACS'), in addition to the patient's medical record.

Finally, the medico-legal responsibilities of the referring hospital or provider and those of the reporting tele-radiology service must be clearly defined and maintained by the healthcare facility, explicitly detailing who retains responsibility for the care of the patient for not only organisations contracting out tele-radiology services, but also for the patients within the organisations receiving tele-radiology services.

This policy is to be read in conjunction with the DHCA Teleconsultation Policy, mentioned above, and supplements DHCA's Standard for Telehealth Services.

DHA Medical Display Screens Circular - 20 May 2019

The DHA recently issued a circular highlighting that, by the end of December 2019, all medical images must be read only in a DHA licensed healthcare facility on a medical display screen meeting the following minimum requirements:

- liquid crystal display ('LCD') or organic light emitting diode ('OLED') flat panels with medically qualified diagnostic screens;
- pixel pitch and display size should be consistent with the devices used, with a minimum requirement of two megapixel;
- twisted nematic LCD devices should not be used for medical image viewing; and
- the equipment should have a closedloop control circuit.

This circular is likely to be aimed at the various unauthorised telemedicine activities being conducted in the emirate, including doctors using generic smart phones to receive and review medical images.

DHA Patient Referral Policy - 1 April 2019

DHA's new referral policy defines a referral as *"a process in which a healthcare professional at one level of the health system, having insufficient resources (drugs, equipment, skills) to manage a clinical condition, seeks the assistance of a better or differently resourced professional at the same or higher level to assist in or take over the management of the patient; this includes community referral, primary care referral, post-acute referral, and referral for all levels of hospital settings"*.

We often see providers seeking to transfer patients for various reasons, including for the lack of payment of medical bills. The policy clarifies the referral criteria/process, minimum requirements to be set out in a referral form, responsible healthcare professionals' communications, and minimum equipment required to refer the patient as per their acuity.

DHA Code of Conduct for Healthcare Professionals - 1 April 2019

In general, this code reflects provisions set out in various other pieces of law and regulations. A few key prohibitions focus on healthcare professional financial dealings and the avoidance of kickbacks, including:

- kickbacks are strictly prohibited. These include payments given or received by other healthcare professionals, health facilities, or institutions for referring or prescribing tests and/or medications and treatment to patients;
- healthcare professionals are prohibited from offering financial incentives or other valuable incentives to online bloggers to falsify information or mislead the public;
- healthcare professionals may not accept any incentive, gift, or hospitality from patients that may affect or be seen to affect the way they prescribe or treat patients. This includes, but is not limited to, discounts, free purchases, cash, credit, or the like; and
- healthcare professionals are prohibited from basing their decisions, such as admitting, referring, or prescribing tests and/or medications, for the sole purpose of financial gain.

DHA Guidelines for Patient Consent - 2019

Consent before treatment is a legal requirement across the UAE. Consent requirements are set out in various federal and local emirate laws, regulations, and policies.

For healthcare professionals regulated by the DHA, consent must be obtained before undertaking any examination or investigation, providing interventions or treatment, or initiating telehealth services. Further, electronic versions of informed consent forms are considered by the DHA as acceptable, as are electronic signatures if the health facility is using electronic health records.

DHA Guideline for Managing Health Records - 2019

The guideline revises the 2012 Health Record Guidelines and is not obligatory nor exhaustive. It encourages the adoption of best practice for managing health records by all DHA licensed health facilities.

Details concerning method of documentation, management of health records as part of business continuity, transfer of paper based health records to electronic health records, and data protection and confidentiality are the key amendments and updates incorporated in this version.

DHA Standards for Telehealth Services - 2019

In 2017, DHA issued Administrative Decision Number 30 of 2017 to regulate the practice of telehealth services in the Emirate of Dubai, which has now been repealed. This 2019 standard sets 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.

The standard divides telehealth into six key areas:

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

We further discuss this standard in our November 2019 Law Update entitled "[DHA Issues New Standard for Telehealth Services](#)".

DHA Purchasing Emergency Medications Policy - 23 July 2019

DHA licensed healthcare facilities are required to stock the minimum emergency medicines set out in this policy. The policy also addresses the purchase of emergency medications that are not registered by the Ministry of Health & Prevention ('MOHAP') but are required based on a patient's need.

DHA Clinical Privileging Policy - 1 April 2019

Each DHA licensed healthcare facility must have in place a Clinical Privileging Committee ('CPC') that meets the membership composition set out in the policy.

Clinical privileges are to be granted according to the titles detailed in the UAE's Professional Qualification Requirements (the 'PQR'). Clinical privileging is to be reviewed every three years, to include the review of clinical competence, malpractice, incident reporting, and patient outcomes.

DHA - Transfer of Controlled and Semi-Controlled Drugs - 22 July 2019

Transfer of Registered Controlled Drugs ('CD') and Semi-Controlled Drugs ('SCD') between pharmacies and other health facilities is prohibited and is considered an illegal practice. Conditions where transfer is permitted includes:

1. closure of a health facility that is owned by the same owner;
2. emergency cases, transfer of registered CD and SCD within a group of health facilities with the same owner;
3. all transfers of registered CD and SCD must be authorised by the pharmacists in charge of both pharmacies and documented as per DHA requirements; and
4. the transfer process must be completed in two working days, and is subject to DHA inspection.

In line with the DHA Purchasing Emergency Medications Policy of 2019, health facilities with an ongoing drug shortage may seek DHA approval to have in place an agreement with another facility of different ownership to transfer registered CD and SCD for emergency cases.

Narcotics are not permitted to be transferred between health facilities; any such transfer is considered an illegal supply.

DHA Fitness to Practice Policy - 24 July 2019

All healthcare professional applicants (whether for new, renewal, or transfer of a licence) are required to provide a medical fitness document if they are above 65 years of age or have a physical, mental or emotional condition that may impair their ability to render professional services.

The medical director of the health facility is responsible to report to the DHA any healthcare professional identified as unfit to practise.

The DHA will address medical fitness related concerns as per its Medical Complaint Management Policy. The medical related areas of concern include:

1. dealing, possessing, or misusing drugs;
2. working beyond 65 years of age without DHA approval;
3. misleading patients about their care or treatment;
4. failure to obtain proper consent from a patient, where applicable;

5. failure to keep knowledge and skills up-to-date;
6. lack of ability to work within the boundaries of the scope of practice defined by the professional category licence;
7. failure to adhere to the DHA patients' charter; and
8. non-compliance regarding communicable disease testing and restrictions related to professional practice.

All non-medical related areas of concern, such as fraud, criminal offences, and complaints related to conduct are received by DHA, classified, and referred to the concerned department and/or authorities, as appropriate, for action.

DHA Standards for Day Surgery Centres - 2019

The standard includes updates and obligations concerning: healthcare professional and staffing requirements; permitted sedation levels; permitted patient acuity; emergency management and transfer of patients; sedation and procedure requirements; various aspects of patient care and safety including set up; pre-assessment; diagnostics; informed consent; equipment use and maintenance; medication management; records management; infection control; quality control; reporting of key performance data; and patient rights and responsibilities.

All Day Surgical Centres ('DSC') must be accredited by a member of the International Society for Quality in Healthcare ('ISQua'), such as:

- Joint Commission International ('JCI') Ambulatory Care;
- Accreditation Canada International;
- Australian Council of Healthcare Standards International ('ACHSI'); or
- American Association for Accreditation of Ambulatory Surgery Facilities.

A series of annexures provide example documentations, including a surgical safety checklist, DSC care pathway, and minimum requirements for informed consent, amongst others.

DHA Health Facility Guidelines - 2019

DHA issued new planning and design guidelines for healthcare facilities. These guidelines establish the minimum acceptable standards that must be met prior to the approval of a health facility licence, and maintained throughout the terms of the licence. Minor deviations from these guidelines may be proposed to DHA, by briefly describing the reasoning for the deviation based on models of care and unique circumstances.

DHA Guidelines for Medical Advertisement Content on Social Media - 2019

This DHA guidelines set out the requirements for managing medical advertisement content on social media relative to DHA licensed health facilities and healthcare professionals. The guidelines focus on the provision of accurate information that is not misleading.

All social media advertisements should be substantiated, particularly when it relates to the outcome(s) of treatment, whether implied or explicitly stated, and should always include any associated risks. Health facilities and healthcare professionals receiving financial or other material benefit for promoting healthcare or non-healthcare related products or services should disclose such relationships to their healthcare facilities and patients.

The use of any patient information or individual likeness should be accompanied by documented consent, in accordance with the guidelines and DHA consent standards. It is expressly prohibited to video or live stream on any social media platform, any surgery or situation where a patient is induced under general anaesthesia.

Clinical Laboratory Accreditation Policy - 1 April 2019

All new and licensed clinical laboratories under the DHA must be accredited by one of the internationally recognised accreditation organisations mentioned in the policy, including the following types of laboratories:

- free standing clinical laboratories;
- clinical laboratories within diagnostic centres;
- hospital based and ambulatory care services clinical laboratories; and
- blood banks.

DHA licensed clinical laboratories are required to obtain accreditation within 18 months from the issuing date of the health facility licence for all of the tests conducted in the clinical laboratory.

Clinical laboratories are permitted to outsource tests to an accredited clinical laboratory meeting the requirements of the policy, if it does not have the infrastructure/ resources itself.

Conclusion

Across the Middle East, the sector is witnessing a rapid and significant overhaul of its regulatory frameworks as governments in the region issue new or enhanced laws and regulations, increase enforcement, and implement programmes to attract private sector investment.

This year, in the UAE, DHA has had the biggest push for healthcare regulatory overhaul. This has been, in part, driven by the 2018 Dubai law that shifted a number of additional functions to the DHA.

Stay tuned; we expect the pace of reform to keep up into 2020.

Al Tamimi & Company's [Healthcare Practice](#) regularly advises on laws and regulations impacting the healthcare sector. For further information, please contact healthcare@tamimi.com.