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New UAE Law Regulates Healthcare Data

Healthcare entities should assess whether Federal Law No. 2 of 2019 applies to their practices and plan for compliance.

On 6 February 2019, the President of the United Arab Emirates (UAE) in conjunction with the UAE Minister of Health and Prevention (the Minister) issued a new law on the use of information and communications technology (ICT) in health fields in the UAE. Federal Law No. 2 of 2019 (the Law) entered into effect in May 2019 and will likely affect the activities of a number of entities operating in the healthcare sector in the UAE.

Article 2 of the Law states that the Law applies to "all information and communications technology methods and uses in health fields" in the UAE (including free zones). Notably, entities in the UAE that use information technology to process healthcare data, including healthcare service providers, life sciences companies, cloud service providers, healthcare IT systems suppliers, and medical insurance providers, will likely be impacted.

The Law sets out high-level obligations and restrictions but delegates a significant amount of detail on the application of the Law — and, importantly, carve-outs to the application of the Law — to implementing regulations, professional guides, and decisions from the Minister. Such implementing regulations, professional guides, and Ministerial decisions will be key to providing affected entities with a full understanding of the Law.

This *Client Alert* sets out the five key features of the Law with respect to its application to entities that collect, process, and store healthcare data in the UAE; identifies the matters that will be further clarified by the implementing regulations, professional guides, and Ministerial decisions; and flags additional issues that are likely to be addressed in future regulations and guidance.

5 Key Features

1. Healthcare data that is covered

Article 1 of the Law defines "health information" broadly to include information that is processed and given a "visual, audible, or readable indication" and attributed to the health sector. This definition can be read to include a patient's name, date of birth, blood test results, medical imagining results, and information collected and recorded during a consultation, among other information.

2. ICT use and data protection obligations

Pursuant to Article 4 of the Law, organisations that use ICT for healthcare in the UAE need to:

- Keep all health data confidential and allow its circulation only in authorised cases
- Ensure the validity and credibility of the health data by protecting its integrity from destruction or unauthorised amendment, alteration, deletion, or addition
- Ensure the availability of the health data to authorised parties and facilitate access thereto when needed

Article 16 of the Law further requires that whoever circulates information related to patients is to abstain from using that health data for non-health purposes unless the health data is used:

- With the patient's written consent for such use
- By health insurance companies (or any health services funding entity) to approve or verify the financial benefits received by the patient
- For scientific research purposes (provided that the identity of the patient is not disclosed and that any applicable scientific research rules and/or guidelines are complied with)
- To take preventive or curative measures to protect public health, or protect the health and safety of the patient (or any other person related to him)
- At the request of a competent judicial entity
- At the request of a health authority for the purpose of control, inspection, or protection of public health

3. Central system

Articles 5 to 15 of the Law deal with the establishment of a new central system in coordination with the federal and local health authorities to store, collect, and exchange health data (the Central System). Access to the Central System, the prescriptive details as to which entities are required to be authorised to use the Central System, and any necessary administrative steps that must be followed, will be set out in the implementing regulations and professional guides.

4. Data localisation and retention

Article 13 of the Law states that health data related to health services provided in the UAE may not be stored, processed, generated, or transferred outside of the UAE, unless such activity has been approved by a decision of the health authority or the Minister.

In addition, Article 20 of the Law states that health data must be kept for a minimum of 25 years from the date on which the last health procedure was performed on the patient. This period may be longer if it is commensurate with the need to keep such data.

5. Penalties

Articles 23 and 24 of the Law specify certain monetary penalties for:

- Publication of a health advertisement through the Central System without authorisation (with a fine between AED 100,000 and AED 200,000 (approx. US$ 27,000 and US$ 54,000))

- Violation of the data localisation obligation in Article 13 of the Law (with a fine between AED 500,000 and AED 700,000 (approx. USD 136,000 and USD 190,000))

In addition, Article 25 of the Law grants the health authority the right to issue the following disciplinary sanctions:

- An oral and/or written warning
- Additional fines between AED 1,000 and AED 1,000,000 (approx. USD 270 and USD 270,000)
- Temporary suspension (not exceeding five months) from the Central System
- Cancellation of the authorisation to use the Central System

The Law does not provide any guidance regarding when stricter penalties will be applied, nor does it state if the fines are issued per individual breach or whether multiple breaches will be seen as one violation of the Law and therefore subject to the applicable caps.

Such guidance will likely be forthcoming in future implementing regulations and Ministerial decisions.

What to Look for in Future Regulations and Guidance

A full understanding of the Law will depend on publication of the implementing regulations, professional guides, and Ministerial decisions. What entities that are subject to the Law should do pending publication of such regulations and guidance is not clear; however, these entities should adhere to the Law until regulations and guidance permit otherwise.

Key areas that will likely be covered by future regulations and guidance include:

- Procedures for implementing, accessing, and using the Central System (see Articles 7, 8, 14, and 15) and for the retention of heath data (see Article 20)
- Health data storage conditions and controls (see Article 12)
- Exceptions to the data localisation requirements (see Article 13)
- The formation of a disciplinary grievance committee (see Article 26)

Article 29 states that the implementing regulations will be published within six months of the publication date of the Law and, accordingly, the authors of this *Client Alert* anticipate publication on or before September 2019.

Conclusion

The Law, and in particular the data localisation requirements in Article 13, has drawn significant attention in media coverage and raised concern among some overseas medical service providers and healthcare technology providers who are active in the UAE.

Until further guidance is issued, the data localisation requirement will likely impact a number of entities involved in the provision of healthcare services in the UAE who rely on offshore data centres and cloud service providers for the hosting of healthcare data.

Some entities will need to alter the way they collect, process, and store healthcare data in the UAE, which will include upgrading their local IT systems to comply with the prescribed technical controls and procedures and not transferring or storing healthcare data outside of the UAE — steps that may require a significant financial outlay.

That said, the Law also creates opportunities for organisations in the UAE healthcare sector. Being one of the first organisations to meet compliance may result in a first-mover advantage, the effect of which could be securing new business opportunities with other operators in the healthcare sector. In addition, upgrading IT systems is an opportunity to innovate and incorporate concepts such as privacy by design and data portability, improvements that can help build customers' trust and confidence in the organisation's brand and potentially future-proof an organisation's IT environment against any new UAE federal data protection laws.

Latham & Watkins will continue to monitor developments in this sector and will publish an update to this *Client Alert* once the implementing regulations, additional guidance, and/or Ministerial decisions are available.

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