Federal Law No. (2) of 2019 Concerning the Use of Information and Communication Technology (ICT) in Health Fields

We, Khalifa Bin Zayed Al Nahyan, President of the United Arab Emirates,

Having taken cognizance of the Constitution,

- Federal Law No. 1 of 1972 Concerning the Mandates of Ministries, Powers of Ministers and its amendments:
- Federal Law No. 7 of 1975 Concerning the Practice of Human Medicine Profession, and its amendments;
- Federal Law No. 15 of 1980 Concerning Publications and Publishing:
- Federal Law No. 4 of 1983 on the Profession of Pharmacy and Pharmaceutical Institutions;
- Federal Law No. 5 of 1984 on the Practice of some Health Professions by non-Doctors and non-Pharmacists:
- Federal Law No. 3 of 1987 Promulgating the Penal Code, and its amendments;
- Federal Law No.11 of 1992 Concerning the Issuance of the Civil Procedure Code, and its amendments:
- Federal Law No. 35 of 1992 Promulgating the Penal Procedure Law, and its amendments;
- Federal Decree-Law No. 3 of 2013 Regarding the Organization of Telecommunication Sector, and it amendments:
- Federal Law No. 8 of 2004 Concerning the Financial Free Zones;
- Federal Law No. 1 of 2006 on Electronic Commerce and Transactions:
- Federal Law No. 9 of 2006 on the Population Register and the Identity Card, and its amendments;
- Federal Law No. 6 of 2007 on the Establishment of the Insurance Authority and Organization of its Operations, and its amendments;
- Federal Law No. 11 of 2008 Concerning Licensing Fertilization Centers in the State;
- Federal Law No. 18 of 2009 on the Regulation of the Registration of Births and Deaths;
- Federal Decree-Law No. 3 of 2012 on the Establishment of the National Electronic Security Authority;
- Federal Decree-Law No. 5 of 2012 on Combating Cybercrimes, and its amendments;
- Federal Law No. 14 of 2014 on Combating Communicable Diseases;
- Federal Law No. 4 of 2015 Concerning Private Health Facilities;
- Federal Decree-Law No. 4 of 2016 on Medical Liability;
- Federal Law No. 14 of 2016 on Violations and Administrative Penalties in the Federal Government:
- Federal Decree-Law No. 16 of 2016 on the Establishment of the Emirates Healthcare Services Establishment; and
- And in accordance with the presentations made by the Minister of Health, approval of the Cabinet, the Federal National Council, and the ratifications of the Federal Supreme Council;

We have promulgated the following Law:

^{*}In case of any misinterpretation, the Arabic version of this legislation prevails.

In the implementation of the present Law, the following words and expressions shall have the meanings corresponding thereto, unless the context otherwise requires:

In the Application of the provisions of this Law, the following words and expressions shall have the meanings indicated opposite each of them, unless the context requires otherwise:

The State : The United Arab Emirates

MOHAP/ the Ministry : The Ministry of Health and Prevention

The Minister : Minister of Health and Prevention

Health Authority : Any federal or local government health authority in the State

Concerned Authority : Any entity in the State providing health services or health

insurance services, health insurance brokerage services, managing health insurance requirements or electronic services in the healthcare field or any entity related, whether directly or

indirectly, to the implementation of the provisions hereof.

Person : The natural or legal person

Central System : The operations of health information and data electronic

exchange, including the set of electronic parts or elements linked and working together for the achievement of a specific goal.

Data : Anything that may be stored, processed, generated and transferred

through the Information and Communication Technology (ICT),

such as numbers, letters, codes, photos, etc.

Health Information : The health information that were processed and were given a visual, audible or readable indication attributed to the health

sector, whether related to the health or insurance facilities or

entities or to the health services beneficiaries

Processing : The electronic creation, entry, amendment, update or deletion of

the information.

Health Information : The act of examining, exchanging, copying, photocopying,

Circulation transferring, storing, disseminating, disclosing or sending health

data and information.

Instruction Manual : The description of the methods, actions and procedures that

should be used as guidelines.

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Information and Communication Technology (ICT) : The technical or electronic tools or systems or other tools allowing all kinds of processing of information and data, including the ability of storage, retrieval, dissemination and exchange thereof.

Article 2

Scope of Application of this Law

This Law shall apply to all Information and Communication Technology (ICT) methods and usages in the health fields in the State, including Free Zones.

Article 3 Objectives of the Law

This Law aims at the following:

- 1. Ensuring the optimal use of the ICT in health fields;
- Ensuring compatibility of the principles, standards and practices applicable in the State with their internationally recognized counterparts;
- 3. Enabling the Ministry to collect, analyze, and keep the health information at the State level;
- 4. Ensuring the safety and security of health data and information.

Chapter 2

Use Controls of Information and Communication Technology Article 4

ICT Use Obligations

The following conditions shall be adhered to when using ICT in health fields:

- Keeping all health data and information confidential and allowing their circulation only in the permitted cases;
- Ensuring the validity and credibility of the health data and information, by protecting the integrity thereof from destruction or unauthorized amendment, alteration, deletion or addition;
- Ensuring the availability of the health data and information to the authorized parties and facilitating access thereto when needed.

Article 5

Establishment of the Central System

The Ministry shall establish a Central System in coordination with the Health Authority and Competent Authorities to keep, exchange and collect all health information and data.

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Principles, Standards and Controls of Electronic Systems

The Health Authority shall prescribe the principles, standards and controls required for electronic systems of its health information and data, such as the methods of operating these electronic systems, the method of information and data exchange, protection, access and copying, the changes made thereto, auditing thereof, the proper and secure use thereof, and the health information and data risk management.

Article 7

Joining the Central System

The Health Authority and the Competent Authority shall join the Central System as per the controls and procedures prescribed by the executive regulation of this Law.

Article 8

Obligations of Using the Central System

- 1. The entities authorized to use the Central System shall abide by the following:
 - Defining the persons authorized to access and circulate the health information and data systems and rules and designating their powers;
 - Taking all necessary procedures to protect and ensure the safety and confidentiality of the health information and data;
- The executive regulation of this Law shall define the controls and procedures for the implementation of the provisions of this Article.

Article 9

Publication and Distribution of the Instruction Manual

The entity authorized to publish and distribute the Instruction Manual through the Central System shall be determined by virtue of a decision issued by the Minister in coordination with the Health Authority.

Article 10

Coordination between the Ministry and the Competent Authority or Health Authority

The Ministry shall, in coordination with the Health Authority or Competent Authority:

- Develop and implement a national strategic plan for the use of ICT in health fields;
- Develop mandatory mechanisms and procedures for the use of ICT in health fields, in accordance with the provisions of this Law and any other law applicable in the State;
- Implement and evaluate the initiatives and programs defined in the strategy and the technical standards;

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- 4. Develop the controls, standards and procedures of the electronic operational programs used for establishing a connection with the diagnosis and treatment devices of the facilities providing health services:
- 5. Develop the mechanisms and procedures for the circulation of health information and data.

Ensuring Compatibility of Used Information Systems

The Health Authority and Competent Authority shall, each within the scope of its competencies, ensure the validity, credibility, and availability of the health information and data in such a manner ensuring compatibility of the used Information Systems and their interoperability to exchange and collect health information and data.

Article 12

Storage of Health Information and Data in the State

The health information and data storage conditions and controls in the State shall be defined by virtue of a decision issued by the Minister in coordination with the Health Authorities.

Article 13

Storage and Transfer of Health Information and Data Outside the State

The health information and data related to the health services provided in the State may only be stored, processed, generated or transferred outside the State in the cases prescribed by virtue of a decision issued by the Health Authority in coordination with the Ministry.

Article 14

Prohibitions of Using the Central System

No one is allowed to use the Central System before obtaining a permission to this effect by the Health Authority or Competent Authority as per the provisions of the Executive regulation of this Law.

Article 15

Obligations of Using the Central System Use

- 1. The persons authorized to use the Central System shall abide by the following:
- a. Circulate the information required for the accomplishment of the required job or defined objective;
- b. Circulation of the information shall be exclusive to the authorized persons only;
- Amend the health information and data, by way of deletion or addition, only as per the prescribed controls;
- d. Disseminate the health information and data, in addition to the statistics related to the health field, only as per the prescribed controls;

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The Executive regulation of this Law shall prescribe the controls and procedures for the implementation of the provisions of this Article.

Article 16

Confidentiality of Information Related to Patients and Exclusions

Without prejudice to any legislation in force, whoever circulates information related to patients shall keep them confidential and shall abstain from using them for non-health purposes without obtaining a written approval of the patient, the following cases shall be excluded:

- The health information or data required by health insurance companies or any entity funding the provision of health services received by the patient, for the purposes of auditing, approving or verifying the financial benefits related to those services;
- Scientific and clinical research purposes, provided that the identity of patients is not disclosed and that the ethics and rules of scientific research are respected;
- Taking preventive and curative measures related to the public health or for the sake of protecting the health and safety of the patient or any other related person;
- 4. Upon request of the competent judicial entities;
- Upon request of the Health Authority for the purposes of control, inspection and protection of public health.

Article 17

Advertisement Licensing

The Central System may not be used to publish any health advertisement before obtaining license from the Ministry.

Article 18

Violation of the Controls and Standards of Health Advertisements

The Ministry may request the Competent Authority, as per its applicable procedures, to ban or block websites, whether inside or outside the State, which violate the controls and standards in force in the State regarding health advertisements or publish health advertisements and information before obtaining permission or license from the Ministry.

Article 19

Training and Oualification of Human Resources

The Health Authority shall provide training and qualify the human resources and provide the necessary resources and proper environment to ensure the safety and security of health information and data according to the best international practices.

Article 20 Keeping Health Information and Data

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- 1. Keeping health information and data through ICT shall be as per the following:
 - a. The period during which health information and data are kept shall commensurate with the need thereof, provided that it is no less than 25 (twenty-five) years as of the date of the last health procedures provided to the person concerned with such health information and data;
 - Ensuring the application of confidentiality, validity and credibility standards of such health information and data;
- The Executive regulation of this Law shall prescribe the controls and procedures for the implementation of the provisions of this Article.

Inclusion of the Identity Number in Health Transactions and Files

The Health Authority and Competent Authority shall enter the identity number in all health transactions, registers and files and to use the ID number for the purposes of organization and storage thereof, except in the emergency cases and other cases defined by virtue of a decision issued by the Ministry in coordination with the Health Authority.

Chapter 3 Penalties Article 22

Application of the Severer Penalty

The penalties provided for under this Law shall be applied without prejudice to any severer penalty provided for under any other law.

Article 23

Penalty of Unauthorized Advertisement Publication

Whoever publishes a health advertisement through the Central System without obtaining authorization shall be punished by a fine of not less than AED 100.000 (one hundred thousand) and not more than AED 200.000 (two hundred thousand).

Article 24

Penalty of the Violation of Article (13)

Whoever violates the provisions of Article (13) of this Law shall be punished by a fine of not less than AED 500.000 (five hundred thousand) and not more than AED 700.000 (seven hundred thousand).

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Disciplinary Sanctions

Without prejudice to the criminal penalties established under this Law or under any other law, the Health Authority may, within the scope of its competence, punish the institutions that provide health services or work in the field of health research or the facilities authorized to use the Central System and violate the provisions of this Law, its executive regulation, or the decisions issued thereunder, by any of the following disciplinary sanctions:

- a. Written notification:
- b. Written warning;
- Fine of not less than AED 1000 (one thousand) and not more than AED 1.000.000 (one million);
- d. Temporary suspension of the Central System authorization for not more than 6 months;
- e. Cancellation of the Central System authorization.

Article 26

Grieving against Disciplinary Sanctions

- A committee shall be formed at the Health Authority to examine all grievances filed against disciplinary sanctions. This committee shall be formed by virtue of a decision issued by the Health Authority, defining the competences thereof and the way of filing grievances;
- 2. Any person against whom a disciplinary sanction was issued as per Article (25) hereof may submit a grievance against the decision before the Grievances Committee formed at the Health Authority, within 15 (fifteen days) from the date in which the grievant party receives notification of the decision:
- 3. The grievance shall be settled within 30 (thirty days) as of the date of submittal thereof. In the event that no reply is received during this period, the grievance shall be deemed as rejected;
- 4. The decision issued regarding the grievance shall be final;
- 5. A person whom grievance has been rejected may file an appeal before the competent courts in the State within thirty days as of the date of being notified of the grievance rejection or before the expiry of the thirty-day period referred to under Clause (2) hereof.

Chapter 4 Final Provisions Article 27

Judicial Officers

The employees appointed by virtue of a decision issued by the Minister of Justice, in agreement with the Minister or the Health Authority shall have the capacity of judicial officers to prove the violation of the provisions of this Law and the decisions issued pursuant thereto, within the scope of their competencies.

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Regularization of Affairs of the Competent Authorities

The Competent Authority shall regularize their affairs as per the provisions of this Law, within the period prescribed by virtue of a decision issued by the Cabinet.

Article 29

Issuance of the Executive Regulation of the Law

The Cabinet shall issue, based on the proposal of the Minister, the executive regulation of this Law within six months as of the date of its publication.

Article 30

Abrogation of Violating and Contradicting Provisions

All provisions in violation of or in contradiction with the provisions of this Law shall be abrogated.

Article 31

Publication and Entry into Force of the Law

This Law shall be published in the Official Gazette and shall come into force three months after the publication thereof.

Khalifa bin Zayed Al Nahyan President of the United Arab Emirates

Issued by us at Abu Dhabi Presidential Palace Date: Jumada al-Thani 1, 1440 H Corresponding to: February 6, 2019 G

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