Federal Law No. (7) of 2019 Concerning Medically Assisted Reproduction

We, Khalifa Bin Zayed Al Nahyan, President Of The United Arab Emirates,

- Having perused the Constitution;
- Federal Law No. (1) of 1972 concerning the Jurisdictions of Ministries and the Powers of Ministers, as amended;
- Federal Law No. (7) of 1975 concerning the Practice of Human Medicine, as amended;
- Federal Law No. (8) of 1980 concerning the Regulation of Labour Relations, as amended;
- Federal Law No. (5) of 1984 concerning the Practice of some Medical Professions by persons other than Physicians and Pharmacists;
- Federal Law No. (5) of 1985 concerning the Civil Transactions Law, as amended;
- Federal Law No. (3) of 1987 concerning the Penal Code, as amended;
- Federal Law No. (35) of 1992 concerning Penal Procedures Law, as amended;
- Federal Law by Decree No. (11) of 2008 concerning Federal Government Human Resources, as amended;
- Federal Law No. (11) of 2008 concerning the Licensing of Fertilisation Centres in the State;

- Federal Law by Decree No. (5) of 2011 concerning the Law of Governance of Board of Directors, Secretaries and Committees at Federal Government;
- Federal Law No. (14) of 2014 on Fighting Communicable Diseases;
- Federal Law No. (2) of 2015 concerning Commercial Companies, as amended;
- Federal Law No. (4) of 2015 on Private Health Facilities;
- Federal Law by Decree No. (4) of 2016 concerning Medical Liability;
- Federal Law No. (14) of 2016 concerning Administrative Violations and Penalties in the Federal Government;
- Federal Law by Decree No. (16) of 2016 Incorporating Emirates Health Services Establishment:
- Federal Law No. (2) of 2019 concerning the Use of IT and Telecommunications in the Healthcare Sector; and
- Based upon the proposal of the Minister of Health and Prevention, the approval of the Cabinet and the Federal National Council, and the ratification of the Supreme Council of the Federation;

Have promulgated the following law:

Article (1)

Definitions

In the application of the provisions of this Law, the following words and expressions shall have the definitions set forth opposite each, unless the context otherwise requires:

State : The United Arab Emirates.

Ministry : Ministry of Health and Prevention.

Medical Body : Any Federal or Local Government health bodies in the

State.

Centre : The licensed establishment or unit where Assisted

Reproductive Technology is made.

Assisted Reproductive: Medical techniques and procedures which help effectuate

Technology (ART) extracorporeal conception, including all clinical and

biological interventions that are necessary to effectuate

extracorporeal conception.

Concerned Subjects : The person from whom sperm or unfertilised ova are

extracted.

Article (2)

Scope of Application of the Law

The provisions of this Law shall apply to all Centres in the State, including the Centres incorporated in the free zones.

Article (3)

Objectives of the Law

The purpose of this law is to:

- 1. Regulate the practise of work in the field of Assisted Reproductive Technology.
- 2. Protect the community against illegal practises.
- 3. Ensure the utilisation of the most up-to-date Assisted Reproductive Technology.

Article (4)

Competences of the Medical Body

The Competent Medical Body undertakes the following competences:

- 1. Decide on the Centres' licensing applications, determine their level of activity and ensure that they meet the licensing conditions.
- 2. Decide on the licensing application of health profession practitioners employed in the Centres, ensure that they meet the licensing conditions, and determine their duties.
- 3. Supervise and monitor the Centres.
- 4. Decide on the complaints and reports relating to the Centres' field of activity.
- 5. Investigate the violations committed by health profession practitioners and directors of the Centres.
- 6. Impose the necessary administrative penalties on the Centres, directors of the Centres and health profession practitioners in accordance with the legislations in force in the UAE.

Article (5)

Licensing of Centres

Pursuant to the provisions of the above-mentioned Federal Law No. (4) of 2015, a natural or juridical person may not establish, operate or run a Centre within the State unless a license is obtained from the Medical Body in accordance with the conditions and controls set forth in the Implementing Regulations for this Law.

Article (6)

Licensing Conditions in the State

Any natural or juridical person applying for a license to establish a Centre in the State undertakes to provide the competent medical, technical and other administrative resources, as well as the necessary medical equipment as determined by the Implementing Regulations for this Law.

Article (7)

Identifying Assisted Reproductive Technology

The Assisted Reproductive Technology shall be determined based on a decision by the Minister in coordination with the other Medical Bodies. The Techniques so identified may be used only in the licensed Centres.

Article (8)

Conditions & Controls of Practising Assisted Reproductive Technology

Upon practising any of the Assisted Reproductive Technology, the Centres abide by conditions and controls as follows:

- 1. The Assisted Reproductive Technology shall be the most medically-appropriate method of reproduction where corporeal conception has proven unfeasible for at least one year, unless infertility is pre-diagnosed, in which case the one-year wait will be disregarded.
- 2. The spouses shall submit an official document certified by the competent authority substantiating the existence of a matrimonial relationship between them.
- The Assisted Reproductive Technology shall be made with the written consent of the spouses, provided that the consent is given in the Centre and with the attendance of the spouses.
- 4. The Assisted Reproductive Technology shall not endanger the life of the wife or foetus or pose serious health risks to them as medically accepted and confirmed by a certificate from a specialist physician.
- 5. The Assisted Reproductive Technology shall be made by physicians licensed in the field.
- 6. The spouses shall be provided with a detailed explanation about the Medically-Assisted Reproductive Technology chosen, the stages of the operation and the negative implications or potential complications, as well as the cost of the procedure and actual conception rate of similar cases at the same Centre.
- 7. Any other conditions or controls as determined vide a decision by the Minister in coordination with the other Medical Bodies.

Article (9)

Prohibited Practises

The Centres shall be prohibited from performing the following Assisted Reproductive Technology:

- 1. To perform fertilisation using the sperm of the husband and the ovum of an alien woman, and then implant the fertilised ovum into the wife's uterus.
- 2. To perform fertilisation using the sperm of an alien man and the ovum of the wife, and then implant the fertilised ovum into the wife's uterus.
- 3. To perform external fertilisation using the sperm of the husband and the ovum of the wife, and then implant the fertilised ovum into the uterus of a gestational surrogate.
- 4. To perform external fertilisation using the sperm of a man and the ovum of a woman, and then implant the fertilised ovum into the uterus of another woman.
- 5. To perform external fertilisation using the sperm of the husband and the ovum of the wife, and then implant the fertilised ovum into the uterus of another wife of the husband.
- 6. Any other instances identified vide a decision by the Cabinet.

In all events, performing fertilisation or implant is prohibited except between a spouse who maintain an existing matrimonial relationship and in their presence.

Article (10)

Preservation & Fertilisation of Ova

- 1. Several ova required for implantation may be fertilised at any given time as per the conditions and controls identified by the Implementing Regulations for this Law.
- Fertilised ova may be preserved for future reproduction when needed for a period of five
 years, renewable for a similar period, based on a request in writing submitted by the spouse.
- The Centres must take the maximum possible medical or other measures to prevent the
 mixing between ova or the use of same in contravention of the provision of this Law and
 its Implementing Regulations.
- 4. When the remaining fertilised ova are no longer needed, or when a legal or medical impediment arises that would prevent implanting the fertilised ova in the wife, these ova are left without medical attention until they naturally perish, unless otherwise requested by the spouse.

Article (11)

Ova & Sperm Preservation Period

Upon the written request of the Concerned Subjects, the frozen unfertilised ova or sperm may be preserved for a period of five (5) years, renewable for a similar period,

Article (12)

Conditions & Controls for Conducting Assisted Reproductive Technology

When performing Assisted Reproductive Technology, the conditions and controls identified by the Implementing Regulations for this Law and the decisions issued by the Minister must

be complied with, specifically with regard to the following:

- 1. The number of fertilised ova implanted.
- 2. Preservation of frozen fertilised and unfertilised ova and sperm for future conception.
- Approval of the spouse to have the frozen fertilised ova preserved and the approval of the Concerned Subjects to have the frozen unfertilised ova or sperm preserved, with the Medical Body to be informed to that effect.

Article (13)

Destruction of Ova

- 1. Fertilised ova that are not implanted in the wife shall be destroyed in the following instances:
 - a. Death of either spouse.
 - b. Termination of the matrimonial relationship.
 - c. Expiration of the period of preservation without a request for extension.
- 2. Frozen unfertilised ova and sperm must be destroyed in either of the following two instances:
 - a. A request to that effect by the Concerned Subjects.
 - b. Expiration of the period of preservation without a request for extension.

Article (14)

Prohibitions of Use of Ova & Sperm

1. The Centres shall be prohibited from using frozen unfertilised or fertilised ova or sperms for commercial purposes, introducing non-therapeutic genetic editing or disposing of them for the benefit of others, even if the approval of the spouse was obtained.

2. The Centres shall be prohibited from conducting research or experiments on unfertilised or fertilised ova and sperm except after obtaining the written approval of the Concerned Subjects or the spouse, as the case may be, in accordance with the conditions and controls identified by the Implementing Regulations for this Law or by the decisions issued by the Minister, as applicable.

Article (15)

Genetic Diagnosis

Without prejudice to the provisions of Article (14) hereof, with the written consent of spouse, the Centres may be permitted to perform Preimplantation Genetic Diagnosis (PGD) in order to identify hereditary diseases, provided that all necessary measures be taken to keep the fertilised ovum unharmed.

Article (16)

Centres' Staff Obligations

The Centres' staffs abide as follows:

- Assume their duties in the performance of Assisted Reproductive Technology in accordance with acceptable scientific and professional principles and the controls stipulated by the Implementing Regulations for the Law and the decisions issued by the Minister.
- 2. Maintain the confidentiality of data and information of those benefiting from the Assisted Reproductive Technology in accordance with the legislations in force in the State.

Article (17)

Conditions and Controls of Bringing Specimens into the State or Sending Specimens out of the State

It shall be prohibited to send out of the State any specimens of unfertilised or fertilised ova or sperms prepared in the State, or to bring into the State any of these specimens prepared outside the State except in accordance with the controls and procedures identified by the Implementing Regulations for this Law.

Article (18)

Centres Obligations towards Fertilised and Unfertilised Ova and Sperm

The Centres abide by the controls relating to the handling of frozen fertilised or unfertilised ova and sperm and shall exercise the highest degrees of care and precaution so that they may not be used, exploited, replaced or conflicted.

Article (19)

Transfer of Fertilised or Unfertilised Ova and Sperm

Frozen fertilised or unfertilised ova or sperm maintained to perform Assisted Reproductive Technology may not be transferred from one Centre into another except with the approval of the spouse or Concerned Subjects, as the case may be, and subject to the approval of the Medical Body.

Article (20)

Centres Assessment Criteria

A decision shall be issued by the Minister laying down Centres Assessment Criteria in coordination with the other Medical Bodies.

Article (21)

Centres Obligations

The Centres abide as follows:

- 1. Submit an annual report to the Competent Medical Body in accordance with the form laid down by the Ministry in coordination with the other Medical Bodies.
- 2. Ensure quality of performance, especially with regard to the control systems inside the laboratory by adhering to the criteria set out vide a decision issued by the Minister in coordination with the other Medical Bodies.
- Develop and upgrade the competence of their technical staff that is operating in the area
 of laboratory fertilisation in accordance with a training program approved by the
 Medical Body.
- 4. Keep necessary registers to record all the procedures of Assisted Reproductive

 Technology. A decision shall be issued by the Minister in coordination with the other

 Medical Bodies, determining the types and conditions of these registers, and the

 information to be recorded therein.
- 5. Prior to commencing their operation, the Centres shall lay down its by-law, including internal control criteria and mechanism, in accordance with the provisions of this Law, its Implementing Regulations, and any other respective laws and regulations issued in

this respect, provided that the by-law is approved by the Medical Body.

Article (22)

Judicial Officers

The officials who are named by a decision of the Minister of Justice, in agreement with the Head of the Medical Body, shall be designated as judicial officers in relation to any occurrences in violation of the provisions of this Law, its Implementing Regulations and decisions issued in implementation of the Law, each within his own jurisdiction.

Article (23)

Temporary Suspension & Appeal

- 1. By a decision issued by the Medical Body, the Centre may be temporarily suspended until the liability for a violation of this Law, its Implementing Regulations and the decisions issued in implementation of the Law is determined.
- 2. The Centre may appeal the suspension decision to the Medical Body within fifteen (15) days from the date that it is served with the notice of suspension. The appeal must be decided on by the Medical Body within fifteen (15) days from the date of its submission, otherwise the appeal shall be considered as declined, with the decision issued by the Medical Body to be considered as final.

An appeal filed shall not give rise to ceasing the enforcement of the decision on temporary suspension of the Centre's business.

Article (24)

Disciplinary Penalties

Without prejudice to the disciplinary penalties established herein or in any other laws, the Medical Body may, each according to its own jurisdiction, impose the following disciplinary penalties:

- 1. In respect of the violations committed by the Centres in contravention of the provisions of this Law, its Implementing Regulations or the decisions issued in implementation of the Law:
 - a. Written reprimand.
 - b. Written notice.
 - c. A fine of not less than AED. 1000 (UAE Dirhams One Thousand) and not more than AED. 1,000,000 (UAE Dirhams One Million).
 - d. Temporary suspension of the license for a period not exceeding six (6) months.
 - e. Cancelation of the license.
- 2. In respect of the violations committed by the health staff licensed to work at the Centres in contravention of the provisions of this Law, its Implementing Regulations or the decisions issued in implementation of the Law:
 - a. Written reprimand.
 - b. Written notice.
 - c. A fine of not less than AED. 1000 (UAE Dirhams One Thousand) and not more than AED. 500,000 (UAE Dirhams Five Hundred Thousand).
 - d. Temporary suspension of the license for a period not exceeding one (1) year.
 - e. Cancelation of the license.

Article (25)

Appeal

- 1. Whoever a disciplinary action is issued against pursuant to Article (24) of this Law may appeal the decision to the Appeals Committee constituted with the Medical Body within fifteen (15) days from the date he is served with the decision.
- 2. A decision shall be issued on the appeal within thirty (30) days from the date of its submission. In case no reply is given on the appeal during the said period, the appeal shall be considered to be declined.
- 3. A decision issued on the appeal shall be final.

Article (26)

Penal Sanctions

Anyone who violates the provisions of Articles (5), (7), (9), (14), (17) and (19) of this Law is punishable by confinement for no less than two (2) years and no more than five (5) years and a fine of not less than AED. 500,000 (UAE Dirhams Five Hundred Thousand) and not more than AED. 1,000,000 (UAE Dirhams One Million), or by either one of these two punishments.

Article 27

Anyone who violates the provisions of Clauses (3) and (4) of Article (10) or the provisions of Articles (12), (13) and (18) of this Law is punishable by confinement for no less than one (1) year and a fine of not less than AED. 300,000 (UAE Dirhams Three Hundred Thousand) and not more than AED. 500,000 (UAE Dirhams Five Hundred Thousand), or by either one of

these two punishments.

Article 28

Anyone who violates the provision of Article (8) of this Law, or whoever manages or operates a Centre that is temporarily suspended pursuant to Article (23) of this Law with the aim of extending Assisted Reproductive Technology services during the period of suspension, is punishable by confinement and a fine of not less than AED. 200,000 (UAE Dirhams Two Hundred Thousand) and not more than AED. 500,000 (UAE Dirhams Five Hundred Thousand), or by either one of these two punishments.

Article (29)

No Prejudice to Stiffer Punishment

The punishments provided for in this Law shall not prejudice any other stiffer punishment provided for in any other law.

Article (30)

Closure of Centres

In the case of conviction, a court may order the closure of the Centre.

Article (31)

Procedures Taken in case of Closure of a Centre

In the event of closure of the Centre, the issue of a decision on its closure or suspension or

considering its license terminated by operation of the law, the Medical Body shall take the procedures necessary to protect the frozen fertilised and unfertilised ova and sperm and the rights of the patients treated in the Centre or those who continue to receive treatment, especially with regard to ensuring that the necessary medical services continue to be extended to them.

Article (32)

Obtaining the Necessary Licenses

The obtaining of a license in accordance with the provisions of this Law and its Implementing Regulations shall not exempt from obtaining other licenses as required by applicable federal and local legislation.

Article (33)

Establishing a National Committee

The Cabinet shall have the right to constitute a competent National Committee to undertake the duties of submitting recommendations and proposals pertaining to the area of activity of the Centres and coordinate between the Medical Bodies in all pertinent matters, with the constitution decision to set forth the membership and modus operandi of the Committee.

Article (34)

Implementing Regulations for the Law

1. The Cabinet, based on a proposal by the Minister, shall issue the Implementing Regulations for this Law within six (6) months from the date of its publication.

2. The Minister shall issue any other decisions necessary for the enforcement of the provisions of this Law and its Implementing Regulations.

Article (35)

Repeals

- 1. Federal Law No. (11) of 2008 concerning Licensing of Fertilisation Centres in the State shall be repealed. However, the decisions in implementation of the said Law shall continue in force until such time as the Implementing Regulations and the decisions in enforcement of this Law are issued without being in contravention therewith.
- 2. Any provision in contravention or conflict with the provisions of this Law shall be repealed.

Article (36)

Publication & Coming into Force

This Law shall be published in the Official Gazette and shall come into force on the date following its publication.

Khalifa Bin Zayed Al Nahyan

President of the United Arab Emirates

Promulgated at Abu Dhabi, UAE Presidential Palace

On:22 Rabi' Thani 1441 H

Corresponding to: December 19, 2019