

Federal Law No. (11) of 2008

Concerning Licensing of Fertilization Centers in the State

We, Khalifa Bin Zayed Al Nahyan, President of the State of The United Arab Emirates, upon consideration of the Constitution,

And Federal Law No. (1) of 1972, concerning the Jurisdictions of Ministries and the Powers of Ministers, as amended,

And Federal Law No. (7) of 1975, concerning the Practice of Human Medicine, as amended,

And Federal Law No.(5) of 1984, concerning the Practice of some Medical Professions by persons other than Physicians and Pharmacists,

And Federal Law No.(5) of 1985, concerning the Civil Transactions Law, as amended,

And Federal Law No.(3) of 1987, concerning the Penal Code, as amended,

And Federal Law No.(35) of 1992, concerning Penal Procedures, as amended,

And Federal Law No.(2) of 1996, concerning Private Medical Facilities, as amended,

And Federal Law No.(21) of 2001, concerning Civil Service in the Federal Government, as amended,

And based upon the proposal of the Minister of Health, 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

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

State: the United Arab Emirates

Ministry: the Ministry of Health

Medical Body: The Ministry of Health or any other bodies concerned with health affairs in the emirates.

Minister: the Minister of Health

Committee: the Fertilization Centers Oversight and Control Committee

Centre: the Fertilization Centre where assisted reproductive techniques are performed, including all clinical and biological procedures that are necessary to effectuate extracorporeal conception.

Assisted: the medical procedures that are necessary to Reproductive effectuate extracorporeal conception and Techniques reproduction.

Article 2

This Law shall apply to Fertilization Centers operating, or applying for a license to operate, in the State.

Article 3

- a. A Technical Committee shall be appointed by a Cabinet decision upon the proposal of the Minister. The Committee is responsible for the oversight and control of Fertilization Centers in the State. It shall be under the Ministry, and its membership shall comprise technical, Sharia (Islamic law) and legal members. The implementing regulation shall set forth the membership and modus operandi of the Committee.
- b. The Committee's headquarters shall be located in the Ministry of Health.
- c. The compensation of the chairman and members of the Fertilization Centers Oversight and Control Committee shall be determined by a Cabinet decision upon the proposal of the Minister.
- d. The Committee members shall serve a three-year renewable term.
- e. The Committee's recommendations shall be approved by the Minister, and may be appealed to the Minister within fifteen days from the date that they are notified to the concerned party. Appeals must be ruled on within fifteen days from the date that they are submitted, and the aggrieved party may seek legal recourse within thirty days from the date that the rejection of appeal is notified to him, or the date that the time prescribed for ruling on the appeal has elapsed.

Article 4

The Fertilization Centers Oversight and Control Committee shall perform the following responsibilities:

1. To recommend licensing of fertilization, embryos and infertility treatment units, and determine their activity level having ensured that they satisfy the licensing conditions.
2. To review methods and procedures of fertilization, embryos and infertility treatment, and determine and approve their conditions that will be issued by a Cabinet decision pursuant to this Law.
3. To form a technical committee that will be tasked with ensuring that licensing conditions are met, reports and complaints reviewed, oversight of Fertilization

Centers performed, and any matters referred by the Oversight Committee considered. The compensation of technical committees shall be fixed by the

1. Minister of Health.
4. To perform any other duties assigned pursuant to this Law and its implementing regulation or by a Cabinet decision. The Committee may seek advice from experts, scientific societies or centers, or specialized authorities with regard to matters referred to it.

Article 5

A natural or juridical person may not establish, operate or run a Centre within the State without first obtaining a license from the Ministry according to the conditions and controls set forth in this Law and its implementing regulation and decisions.

Article 6

Subject to the provisions of the private medical facilities law, hereinabove mentioned, no center may be licensed within the State without first verifying the technical conditions and specifications and the availability of medical equipment and devices as determined by the implementing regulation of this Law.

Article 7

Any person applying for a license to establish a Center in the State must undertake to provide the medical, technical and other administrative resources as determined by the implementing regulation of this Law.

Article 8

Assisted Reproductive Techniques shall include the following:

1. Intra Uterine Insemination (IUI)
 2. In Vitro Fertilization (IVF), or Intracytoplasmic Sperm Injection (ICSI) and subsequent use of ovum.
 3. Gamete Intra-Fallopian Transfer (GIFT), or Zygote Intra-Fallopian Transfer.
 4. Any universally accepted fertilization techniques, as determined by a Cabinet decision upon the proposal of the Oversight and
1. Control Committee.

Article 9

When performing Assisted Reproductive Techniques, a Centre licensed under this Law shall comply with the following conditions and controls:

1. The Assisted Reproductive Technique shall be the only method of reproduction where corporeal conception has proven unfeasible for at least one year, unless infertility has been prediagnosed, in which case the one-year wait will be disregarded.
2. The Assisted Reproductive Technique shall be performed with the written consent of the husband and wife.

3. The husband shall confirm the existence of a matrimonial relationship by presenting an official marriage certificate upon fertilization and implantation of a fertilized ovum.
4. The Assisted Reproductive Technique shall not endanger the wife's life, or pose serious health risks to her as medically accepted and confirmed by a certificate from a specialist physician.
5. The Assisted Reproductive Technique shall be performed by trustworthy specialists pursuant to the implementing regulation of this Law.
6. The Assisted Reproductive Technique shall be performed in presence of the husband at the Fertilization Centre.
7. Any other conditions or controls as determined by the Cabinet.

Article 10

The Centre shall be prohibited from performing the following Assisted Reproductive Techniques methods:

1. To perform fertilization using the sperm of the husband and the ovum of an alien woman, and then implant the fertilized ovum into the wife's uterus.
2. To perform fertilization using the sperm of an alien man and the ovum of the wife, and then implant the fertilized ovum into the wife's uterus.
3. To perform external fertilization using the sperm of the husband and the ovum of the wife, and then implant the fertilized ovum into the uterus of a gestational surrogate.
4. To perform external fertilization using the sperm of a man and the ovum of a woman, and then implant the fertilized ovum into the uterus of another woman.
5. To perform external fertilization using the sperm of the husband and the ovum of the wife, and then implant the fertilized ovum into the uterus of another wife of the husband.

Article 11

The Centre shall comply with the following with regard to the excess ova:

1. To preserve unfertilized ova for future use as necessary, and fertilize only those ova required for implantation at any given time so as to avoid having surplus fertilized ova.
2. In the case of surplus fertilized ova in whatever manner, these ova shall be left without medical attention until they perish naturally.

Article 12

The Centre must fully inform the husband and wife of the various assisted reproductive techniques and any potential side effects or consequences of each technique, the financial cost involved, and the actual conception rate in similar cases at the same Centre.

Article 13

When performing Assisted Reproductive Techniques, the Centre must comply with the following:

1. The number of transferred embryos or ova shall not exceed three if the wife is thirty five (35) years of age or under, nor shall it exceed four for older wives.
2. To preserve frozen unfertilized ova and sperms for future reproduction for the benefit of husband and wife, for a maximum period of five years in accordance with the terms and conditions stipulated by the implementing regulation of this Law.
3. To obtain the written consent of husband and wife annually with regard to their desire to continue having the frozen unfertilized ova and sperms preserved record same in the laboratory register, and notify the Ministry accordingly.
4. To destroy the fertilized ova that have not been implanted inside the wife and the frozen unfertilized ova and sperms upon the death of either spouse or in the event of divorce, by leaving them without medical attention.
5. To destroy frozen unfertilized ova and sperms upon the request of husband and wife.

Article 14

The Centre or any other body of whatever capacity shall be prohibited from using unfertilized or fertilized ova or sperms for commercial purposes, or conducting research, or executing genetic modifications of the characteristics of neonates, or disposing of them for the benefit of others.

Article 15

Without prejudice to article (14) hereof, with the written consent of husband and wife, the Centre may be permitted to perform preimplantation genetic diagnosis in order to identify hereditary diseases, provided that all necessary measures be taken to keep the fertilized ovum unharmed.

Article 16

The Centre shall undertake to develop and upgrade the competence of its technical staff who are operating in the area of laboratory fertilization in accordance with a training program approved by the Ministry.

Article 17

The Centre's management, laboratories and officers responsible for embryo incubators must participate in the performance of Assisted Reproductive Techniques in accordance with acceptable scientific and professional principles and the controls stipulated by the implementing regulation of this Law.

Article 18

The Centre shall be prohibited from sending out of the State any specimens of unfertilized or fertilized ova or sperms that have been prepared in the State. The Centre shall be prohibited from bringing into the State any of these specimens that have been prepared outside the State.

Article 19

The Centre must undertake to regulate the process of maintaining sperms, unfertilized and fertilized ova and embryos, and exercise the highest degrees of care and precaution so that they may not be used, exploited or replaced hence leading to a mix-up in the lineage.

Article 20

It shall be prohibited to establish or deal with embryo banks in the State.

Article 21

The implementing regulation of the Law shall lay down the criteria for assessing fertilization centers and the reasons for cancelling or suspending their licenses.

Article 22

The Centre shall undertake to submit to the Ministry an annual report showing the number of fertilization procedures performed, the kinds thereof and the success rates achieved.

Article 23

The Centre shall undertake to ensure quality of performance, especially with regard to the control systems inside the laboratory by adhering to the criteria set out in the implementing regulation of this Law.

Article 24

The Centre shall undertake to keep necessary registers to record all the procedures of Assisted Reproductive Techniques. The implementing regulation of this Law shall determine the types and conditions of these registers, and the information to be recorded therein.

Article 25

The Centre, prior to commencing its operation, shall lay down its by-law in accordance with the provisions of this Law, its implementing regulation and any other respective laws and regulations.

Article 26

The officials who are named by a decision of the Minister of Justice, in agreement with the Minister or local health bodies, shall be designated as judicial officers in relation to any occurrences in violation of the provisions of this Law, its implementing regulation and decisions, each within his own jurisdiction.

Article 27

1. Government fertilization centers may be established in accordance with the conditions and controls laid down in this Law and its implementing regulation with regard to Assisted Reproductive Techniques.
2. The implementing regulation of this law shall lay down the necessary procedures and controls for licensing non-governmental bodies opting to practice the business of the Centre as set out in this Law and its implementing regulation.

Article 28

The operation of the Centre may be temporarily suspended until such time as the liability for a violation of this Law has been determined. Suspension shall be by a decision of the Ministry. The Centre may appeal the suspension decision to this authority within fifteen days from the date that it is issued. The appeal must be decided on within one week from the date that it is submitted. The aggrieved party may seek legal recourse within thirty days from the date that a notice of rejection of appeal has been served on it, or the date that the time prescribed for deciding on the appeal has expired.

Article 29

Anyone who violates articles (5), (9), (10), (14), (18) and (20) of this Law is punishable by confinement for no less than two years and no more than five years and a fine of not less than two hundred thousand Dirhams and not more than five hundred thousand Dirhams, or by either one of these two punishments.

Article 30

Anyone who violates articles (13) and (19) of this Law is punishable by confinement for no less than one year and a fine of not less one hundred thousand Dirhams and not more than three hundred thousand Dirhams, or by either one of these two punishments.

Article 31

Anyone who violates any other provision of this Law and its implementing regulation and decisions is punishable by confinement and fine or by either one of these two punishments.

Article 32

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

Article 33

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

Article 34

The obtaining of a license in accordance with the provisions of this Law and its implementing regulation shall not exempt from obtaining other licenses as required by applicable federal and local laws, regulations and rules.

Article 35

The Centers that are already established in the State shall adjust their status in accordance with this Law within a maximum period of six months from the date of this Law coming into effect.

Article 36

The Cabinet shall issue the implementing regulation of this Law.

Article 37

This Law shall be published in the official gazette and shall come into force on the date that it is published.

Khalifa Bin Zayed Al Nahyan

President of the United Arab Emirates

Issued by Us at the Presidential Palace in Abu Dhabi

On: 18 Zil Hijjah 1429 H, corresponding to :16 December 2008