**Law No. (26) of 2017**
**With Respect to The Use of Medical Techniques**
**Assisting in Artificial Insemination and Fertilization**

**We, Hamad bin Isa Al Khalifa, King of the Kingdom of Bahrain.**

Having reviewed the Constitution,

The Penal Code promulgated by Legislative Decree No. (15) of 1976, as amended,

Legislative Decree No. (2) of 1987 with respect to The Practice of Assisting Medical Professions by Non-doctors and Pharmacists,

Legislative Decree No. (7) of 1989 with respect to the Practice of Human Medicine and Dentistry,

Legislative Decree No. (18) of 1997 with respect to the Profession of Pharmacy and Pharmacy Centers, as amended by Legislative Decree No. (20) of 2015,

the Criminal Procedures Law promulgated by Legislative Decree No. (46) of 2002, as amended,

Law No. (38) of 2009 Establishing the National Authority for Regulating Health Professions and Services, as amended by Legislative Decree No. (32) of 2015,

and Legislative Decree No. (21) of 2015 with respect to Private Health Institutions,

The Shura Council and the Council of Representatives approved the following Law, which we have ratified and enacted:

**Chapter One**

**General Provisions**

**Article (1)**

For the purposes of implementing this Law, the following words and expressions shall have the meanings assigned hereunder, unless the context otherwise requires:

**Council**: The Supreme Council of Health.

**Council Chairman**: Chairman of the Supreme Council of Health.

**Authority**: National Health Regulatory Authority.

**Chief Executive Officer (CEO):** The Chief Executive Officer of the National Health Regulatory Authority.

**Committee**: The committee formed by a decision of the Chairman of the Council after the approval of the Council.

**Medical Techniques Assisting in** **Artificial Insemination and Fertilization**: Medical methods which facilitates pregnancy without natural contact.

**Health Institution**: Any hospital, department, or center equipped to use medical techniques assisting in Artificial Insemination and Fertilization, including gynecology and obstetrics clinics that treat infertility, stimulate and monitor ovulation.

**Infertility**: It is the absence of pregnancy and consequently the inability of the spouses to have children after twelve months of continuous marital life in the marital home and without the use of contraceptives for pregnancy or upon prior diagnosis of infertility or difficulty in conceiving.

**Gender Selection of the Fetus**: Intervention to determine the gender of the fetus, using Medical Techniques Assisting in Artificial Insemination and Fertilization.

**Fetus**: The first stages of pregnancy which follows the development of the embryo.

**Gametes**: the combination between the sperm and the woman's egg, which is called (the fertilized egg).

**Eugenic Selection**: Determination of the genetic characteristics of the fetus by means of Medical Techniques assisting in Artificial Insemination and Fertilization, for genetic examination of the embryos; For selection before implantation into the uterine cavity.

**Destruction**: Leave the gametes and embryos unattended until their life ends.

**Artificial insemination**: An injection of a sample of sperm extracted from the husband's sperm into the womb of the wife during the natural or artificial ovulation process.

**Intracytoplasmic Sperm Injection (ICSI):** The injection of one sperm into an egg with a special needle and with the help of a special device with a reflecting microscope.

**In-Vitro-Fertilization (IVF):** Fertilizing the egg of the wife with the husband's sperm in a culture medium.

**Pregnancy**: Conception, fertilization, implanting and development of the fetus inside a woman's uterus.

**Reduction**: It is a selective reduction of embryos for medical reasons to reduce multiple twin pregnancies to twin or mono twin pregnancies, provided that not all embryos are reduced.

**Article (2)**

The provisions of this Law apply to all health institutions that use medical techniques activities assisting in Artificial Insemination and Fertilization.

Owners of existing institutions must submit requests to regulate the conditions of their institutions and license them in accordance with the provisions of this Law within a period not exceeding six months from the date which the provisions come into effect.

**Chapter Two**

**Advisory Committee**

**Article (3)**

A technical advisory committee shall be formed consisting of specialists, by a decision issued by the Council Chairman, after the approval of the Council, and it shall be concerned with examining the licensing requests referred to it from the CEO, including renewal of licenses in accordance with the provisions and procedures stipulated for by the Law, or all issues related to the provisions of this Law.

The Committee meets at the invitation of the CEO, its Council Chairman or the deputy in his absence whenever the need arises, and its meeting is valid in the presence of a majority of its members, provided that the Council Chairman or the deputy is among them, and its recommendations are issued by the majority of the members present, in the event the votes are equal, the side which the chairman voted shall prevail.

The Committee may invite any person it deems appropriate with expertise and specialty to attend its meetings to seek their opinion on matters submitted to it without having the right to participate in voting.

The Committee issues its recommendation to accept or reject the license application, or in matters referred by the Council Chairman. In the event of a refusal, the decision must be justified. The Committee prepares reports of its work and the recommendations it reached and submits it to the CEO to take the appropriate decision in accordance with the powers and competences legally assigned to the CEO.

The term of membership is three years, renewable for a similar period.

**Chapter Three**

**License**

**Article (4)**

Subject to all the provisions of Legislative Decree No. (21) of 2015 with respect to the Private Health Institutions regarding Procedures and Conditions for Licenses, Obligations, Duties, Inspection, Supervision, Investigation and Accountability of Health Institutions and Private Centers subject to the provisions of this Law:

1. No natural or legal person may establish, operate, or manage a health institution except after obtaining a license issued by the Authority in accordance with the conditions and regulations stipulated for in this Law and the relevant laws, and the implementing regulations of this Law.
2. It is prohibited to practice such activity except after acquiring the administrative staff and the specialized medical staff in accordance with the requirements issued by the Authority.

**Chapter Four**

**Medical Techniques Assisting in Artificial Insemination and Fertilization and its Conditions of Use**

**Article (5)**

Medical Techniques Assisting in Artificial Insemination and Fertilization are used in one of the following ways which shall not conflict with the Sharia’a:

A- Artificial insemination.

B- Intracytoplasmic Sperm Injection (ICSI).

C- In-Vitro-Fertilization (IVF).

D- Any other internationally approved technique determined by the Authority based on specialized studies and the opinion of consultants in this field, and after the approval of the Supreme Council for Islamic Affairs.

**Article (6)**

Health institutions are obliged when using medical techniques assisting in Artificial Insemination and Fertilization with the following:

1. The Verification of the existence of a marriage contract notarized by the competent authorities prior to starting and during treatment until embryo implantation, and attach an identical copy of the original in the medical file. In the event of death of one of the spouses is known or the marital relationship ends for any reason, it is necessary to refrain from conducting the process of insemination, fertilization or ICSI and all freezing programs related to their embryos and destroy them in a way that is scientifically recognized.
2. Informing the spouses of the expected success rates and the possibility of resorting to several attempts and the effects and risks to the health of the mother and the fetus.
3. The written consent of the spouses to conduct a medical technique to help artificial insemination and fertilization according to the template prepared by the Authority.
4. The written consent of the spouses on the embryo implantation that are as a result of gametes according to the template prepared by the Authority.
5. Open private records, to be ratified first by the Authority, and then to include all the data and the actions taken and their causes and consequences, and these records may not be destroyed for any reason.
6. Open a file for each case recording the results of the tests and analyzes and medical procedures, medical prescriptions, and everything related to the diagnosis of the case, and is kept for a period of fifteen years from the date of the last medical procedure.
7. Comply with all conditions issued by a decision of the Council.
8. Ensure the completion of a test for hepatitis C and HIV directly to the spouses before treatment, or any emerging tests required by the Authority.

**Article (7)**

It shall be prohibited for the health institution, consultant doctor, specialist, or technologist specializing in embryology from carrying out the following actions:

1. Intrauterine Insemination, except in licensed health institutions using medical techniques to help Artificial Insemination and Fertilization, and the physician has a license to do so.
2. Inseminating sperm other than that of the husband or the fertilization of an egg other than that of the wife.
3. Cloning for any reason.
4. Gender or Eugenic Selection, unless it is for reasons of genetic disorders associated with the gender of the fetus.
5. Obtaining embryos for the purpose of conducting studies and research.
6. Surrogacy, implanting fertilized embryos resulting from an external insemination between the sperm of the husband and wife's egg and then the implantation in the womb of another woman, even if this woman is a second wife to the husband.
7. Transfer more than two embryos into the womb of the wife under the age of thirty five years, three embryos may be transferred if the wife is over the age of thirty five years, as of the day of the transfer.
8. Conducting operations to reduce the number of embryos in the womb, except in cases of necessity to preserve the life of the mother and based upon a joint report prepared by three doctors who are specialized consultants, one of whom shall be from a government hospital, and after taking the written consent of the mother, inability to do so shall result in the legal guardian of the mother to give such written consent. Otherwise the reduction operation is considered to be an abortion.
9. The use of medical techniques for the purpose of donation or sale of gametes or embryos.
10. The inducing of ovulation by the doctor when the doctor is unable to deal with the complications of such inducement.
11. Conduct clinical trials unless it is within the legal framework and in accordance with the applicable conditions and rules in force by the Authority.
12. The use of stem cells derived from a person to treat another person’s infertility.
13. Use of medical techniques to help Artificial Insemination and Fertilization if they pose a threat or irreparable damage to the life of the wife or her health, according to customary medical protocols.

**Chapter Five**

**Preserve Eggs, Embryos, Sperm, or Tissues**

**for the Purpose of Future Fertilization**

**Article (8)**

In order to preserve eggs, embryos, sperm or tissues for the purpose of Artificial Insemination and Fertilization or implantation in the future, the following conditions shall be met:

1. The written consent of the spouses to preserve their embryos. In the event the marital relationship comes to an end, the embryos shall be destroyed.
2. The written consent of the husband to preserve his sperm.
3. The written consent of the wife to preserve her eggs and her own tissues.

The written approval stated in paragraphs (A, B and C) is preserved in the medical file of the husband or wife, as the case may be.

1. The freezing procedure shall be in accordance with the standards issued by the Authority.
2. The freezing of sperm, eggs and tissues for a period not exceeding ten years, and the freezing of embryos for a period not exceeding five years.

The husband has the right to request the destruction of the sperm which he previously requested to have frozen, and the wife is also entitled to request the destruction of the eggs which she previously requested to have frozen. Embryos may not be destroyed except after the consent of the spouses or from the date of the end of the marital relationship or the death of either spouse.

1. In all events, the wife’s eggs shall be destroyed in the event of her passing.

**Article (9)**

Without prejudice to the right of the health institution to carry out the freezing of embryos, sperm or eggs in accordance with the provisions stipulated for in this Law and the regulations and implementing decisions issued pursuant to it, it is prohibited to:

1. Establish an embryo or sperm bank in the Kingdom of Bahrain.
2. Export any embryos, sperm or eggs from the Kingdom of Bahrain or to import embryos, sperm or eggs to the Kingdom.

**Article (10)**

In the event the health institution is closed or its license revoked, it must transfer, with the approval of the relevant parties, the embryos, sperm and frozen eggs to another health institution authorized to practice the activity inside Bahrain, under the supervision and coordination of the Committee, provided that the health institution that was closed or had its license revoked shall be liable for the costs of transport and freezing, and notifying the Authority to assign one of its inspectors to attend during the completion of the transportation procedures.

**Article (11)**

The employees authorized by the Minister concerned with justice affairs in agreement with the Council Chairman shall have the capacity of Judicial Investigation Officers, with respect to the crimes stipulated for in this Law, which fall within their jurisdiction, and related to the work of their job, and the records prepared for these crimes shall be referred to the Public Prosecution by a decision of the CEO of the Authority.

**Chapter Six**

**Penalties**

**Article (12)**

Whomever violates the provision of Article (4) of this Law shall be punished with imprisonment for a period of not less than a year and not exceeding three years, and a fine not less than five thousand dinars and not exceeding ten thousand dinars.

**Article (13)**

Whomever violates the provision of Article (6) of this Law shall be punished with a fine not less than five hundred dinars and not exceeding three thousand dinars.

**Article (14)**

Whomever violates the provisions of paragraphs (A, B, C, F, H, L, M) of Article (7) of this Law shall be punished with imprisonment for a period of not less than three years and not exceeding ten years and a fine not less than ten thousand dinars and not exceeding twenty thousand dinars.

**Article (15)**

Whomever violates the provisions of paragraphs (D, E, G, I, J, K) of Article (7) of this Law shall be punished with a fine not less than one thousand dinars and not exceeding five thousand dinars.

**Article (16)**

Whomever violates the provisions of Articles (8, 10) of this Law shall be punished with, either or both, imprisonment for a period not exceeding three months and a fine not less than three thousand dinars and not exceeding ten thousand dinars.

**Article (17)**

Whomever violates the provisions of Article (9) of this Law shall be punished with imprisonment for a period not less than a year and a fine not less than ten thousand dinars and not exceeding twenty thousand dinars.

**Article (18)**

Without prejudice to the responsibility of the natural person, the legal person is criminally responsible if any of the crimes stipulated for in this Law is committed in their name or on their account, and by one of their apparatus, representatives, or one of their employees, and they are sentenced to a fine equivalent to the established fine for the crime that occurred.

In the event of a conviction, the court may order the suspension of the health facility activity related to the crime for a period not exceeding one year, and in the event of a repeat crime, the court may suspend the activity of the health institution for a period not exceeding five years or revoke the license issued to practice the activity permanently.

The summary of the judgment may be published in two daily newspapers at the expense of the convict.

**Chapter Seven**

**Final Provisions**

**Article (19)**

The Council Chairman shall issue the implementing regulations for this Law, after the approval of the Council, within six months from the date of its publication in the Official Gazette.

The Council Chairman shall also issue the decisions necessary to implement the provisions of this Law.

**Article (20)**

The Prime Minister and the Ministers - each within his jurisdiction - shall implement this Law, and it shall come into force from the day following the date of its publication in the Official Gazette.

**King of the Kingdom of Bahrain**

**Hamad bin Isa Al Khalifa**

Issued in Riffa Palace:

Date: 4 Dhu al-Qi'dah 1438 AH

Corresponding to 27 July 2017