

## **Cabinet Resolution No.25/2020**

### **On the Executive Regulations of the UAE Federal Decree Law No. 5/2016 On Regulation of Human Organs and Tissue Transplantation**

#### **The Cabinet:**

- Having perused the Constitution,
- The Federal Law No.1/1972 on the scope of competencies of the ministries and the powers of the ministers as amended,
- The UAE Federal Decree Law No. 5 /2016 on regulation of human organs and tissue transplantation, and
- On the basis of what has been demonstrated by the Minister of Health and Prevention and following the approval of the Cabinet,

#### **Has decided:**

#### **Article (1)**

##### **Definitions**

The definitions mentioned in the said UAE Federal Decree Law No. 5/2016 shall be applied. Otherwise, the following terms and sentences shall have the meanings corresponding thereto; unless the context otherwise implies:

**The Ministry:** The Ministry of Health and Prevention (MOHAP).

**The Decree Law:** The UAE Federal Decree Law No. 5/2016 on regulation of human organs and tissue transplantation,

#### **Article (2)**

##### **Requirements for licensing medical facilities**

1. A medical facility willing to perform operations for human organs and parts thereof and tissue transplantation shall obtain a license therefor from the competent medical authority prior to practicing any activity in such field.
2. For obtaining the license mentioned in Clause No.(1) of this Article, the facility shall contain medical equipment, requirements, human resources and

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infrastructure required for carrying out such activity in proportion to the field it seeks to occupy in line with the requirements specified in the appendix attached hereto.

### **Article (3)**

#### **Requirements for licensing physicians and procedures thereof**

1. A physician performing an operation for human organs and parts thereof and tissue transplantation shall be licensed for such purpose by the competent medical authority prior thereto.
2. For a physician to obtain the said license, the physician shall:
  - A. Have a competency recognized by the medical authority in order to perform operations for human organs and parts thereof and tissue transplantation based on its experience in such field or based on its receipt of a proper training thereof as per the category of the human organs or tissues that fall under its practices and scope of works.
  - B. Sign an acknowledgement stating its familiarity and compliance with the legislation applicable in the State regarding the field of human organs and tissues transplantation.
  - C. Any other requirements or regulations set by the medical authority.

### **Article (4)**

#### **Requirements for renewing the license of a medical facility**

For the license of a medical facility to be renewed:

1. The requirements stated in Clause No.(2) of Article (2) hereof shall be fulfilled.
2. A detailed scientific report shall be submitted annually to the Ministry of Health and Prevention clarifying the transplantation results in the medical facility in line with the data specified by the Ministry of Health and Prevention . Such shall include:
  - A. The medical condition of the patients, who had a human organ or tissue transplantation operation performed thereon.
  - B. The condition of the transplanted organ.

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C. The rate of complications resulting from the transplantation operation in comparison to the international standards and procedures thereof.

3. Any other requirements set by the medical authority; provided that such shall include the minimum number of operations performed by the medical facility in accordance with standard medical practices.

#### **Article (5)**

##### **Reciprocal transplantation**

For a reciprocal transplantation operation to be performed:

1. It is required that there are two patients, who need an organ or tissues transplantation. They shall not have any kinship up to the fourth lineage.

2. A donor of each patient' side shall be present; provided that such shall have a kinship up to the fourth lineage.

3. Each donor shall accept to donate reciprocally to the other patient, with whom it shall not have any kinship as mentioned above.

4. Physicians shall acknowledge that it is medically proper to perform the transplantation operation for the interest of both reciprocal patients.

5. Each donor shall submit an acknowledgment stating that it shall not claim any damages therebetween; regardless of the results of the transplantation operation.

#### **Article (6)**

##### **Requirements for post-death donation approval**

An individual, willing to donate one of its organs or parts thereof or tissue following its death shall be obliged to confirm such within its identity card data in line with regulations and procedures thereof, via registration over the website specified by the Ministry of Health and Prevention , or via stating such in a written will signed by two of full legal capacity individuals in line with the form set by the Ministry of Health and Prevention .

The said provision shall also be applied in cases of any individual not willing to donate one of its organs or parts thereof or tissues following its death. Such

willingness not to have the said procedures carried out shall be proved via the method mentioned in the previous Clause of this Article.

In all cases, willingness to donate an organ or the absence thereof may be altered unconditionally in line with the procedures of this Article.

#### **Article (7)**

##### **Records of individuals willing to donate**

A record shall be set in the Ministry of Health and Prevention to include the names of those willing to donate following their deaths. Such record shall be set using the data recorded at the Identity and Citizenship Authority (ICA) or via the website specified by the Ministry of Health and Prevention therefor.

#### **Article (8)**

##### **Amending the license requirements**

The Minister may amend the requirements mentioned in the appendix attached hereto following coordination with the medical authorities without prejudice to the Decree Law

#### **Article (9)**

##### **Issuance of executive resolutions**

The Minister shall issue the resolutions required to execute the provisions hereof.

#### **Article (10)**

##### **Publication of resolution and enforcement thereof**

This resolution shall be published in the official gazette and shall come into force starting from the day following the publication date thereof.

*Muhammad Bin Rashed Al Maktoum*

*Prime Minister*

Issued:

**Date:** 7<sup>th</sup> Shaaban, 1441,

**Corresponding to:** 31<sup>st</sup> of March, 2020

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## APPENDIX

### Attached to the Cabinet Resolution No.25/2020 on the Executive Regulations of the UAE Federal Decree Law No. 5/2016 on Regulation of Human Organs and Tissue Transplantation

#### **Requirements for licensing private medical facilities performing operations for human organs and tissues transplantation**

##### **First: Kidney Transplantation**

###### **1. Requirements of technical team:**

The technical team shall be made up of the following:

- A. A kidney transplantation consultant: with an experience of not less than one year working for a recognized kidney transplantation center.
- B. A nephrologist: with an experience of not less than one year working for a recognized kidney transplantation center.
- C. A Nursing staff: nurses shall be highly experienced in order to take care of patients during kidney transplantation and thereafter.
- D. A kidney transplantation coordinator: with sufficient experience to fulfil the said duties. It may be one of the said technical team members.
- E. A nutritionist
- F. A social services specialist

###### **2. Requirements of technical preparations:**

The hospital shall be technically equipped with the following:

- A. A heart disease department, a GIT department (with available endoscopes), pulmonary department (with available endoscopes), a medical imaging department, a haematology department, a pathology department, a biological and chemical laboratory, a dialysis unit (preferably equipped with movable devices and equipment) and an intensive care unit (ICU)
- B. Two operation rooms (ORs) minimum

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C. Two rooms minimum for seated patients following a kidney transplantation.

### **3. Requirements of support medical departments:**

The support medical departments of a hospital shall fulfill the following technical requirements:

A. A laboratory: equipped with equipment for all types of routine tests required to assess patient before and after kidney transplantation in addition to tissue analysis equipment, titration of cytotoxic antibodies, titration of medication levels including cyclosporine and alikes thereof.

B. Medical imaging: either via ordinary x-rays, ultrasound imaging, radionuclides diagnosis and computed tomography (CT).

### **4. Requirements of medications:**

The following medications shall always be available in a hospital:

A. Immunosuppressants: calcineurin, azathioprine and prednisolone inhibitors, antimetabolites and rapamycin receptor inhibitor or alikes thereof.

B. Medications used to treat seizures such as: methylprednisolone, anti-lymphocyte globulin (ALG), anti-thymocyte globulin (ATG) and monoclonal antibodies.

C. Fluids used to hydrate muscles such as: urocoline, University of Wisconsin solution or HTK solution.

D. Medications used to treat bacterial, viral, parasitic and fungal infections.

## **Second: Heart Transplantation**

### **1. Requirements of technical team:**

The technical team shall be made up of the following:

A. Heart transplantation consultants: with a sufficient experience in the field of open-heart surgery; working for one of the internationally recognized heart centers. A heart transplantation consultant should have performed a sufficient number of open-heart surgeries using the ventricular assist device (VAD) for not less than 200 cases.

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B. Intensive care unit specialists: with an experience in following up patients after open-heart surgeries, preferably with an experience in following up heart transplantation cases.

C. Heart diseases consultants: with a capacity to perform all cardiac tests either via ordinary means or via advanced ones. Such consultants shall have an experience in following up patients before and after transplantation operations with a competency of taking samples required.

D. A nursing staff: nurses shall be highly experienced in order to take care of patients during heart transplantation and thereafter.

E. An organs transplantation coordinator

F. A nutritionist

G. A social services specialist

## **2. Requirements of technical preparations:**

The hospital shall be technically equipped with the following:

A. Technical departments:

A GIT department, a medical imaging department, a haematology department, a pathology department, a biological and chemical laboratory, a dialysis unit and an immunology department.

B. Two fully equipped rooms minimum; set for open-heart surgeries.

C. Cardiac assistive devices such as: Intra-aortic balloon pump (IABP), cardiopulmonary bypass as well as other assistive devices along with specialised technicians to operate them.

D. An intensive care unit (ICU) for cases of open-heart surgery; a fully equipped unit with availability of isolating patients whenever necessary and a capacity of implanting a pacemaker temporarily or permanently.

E. Availability of the following specialists:

1. A nephrologist with a sufficient experience to follow up organs transplantation cases.

2. An immune diseases specialist with a sufficient experience to follow up heart transplantation cases.
3. A pulmonologist.
4. A physiotherapist to follow up the patient's respiratory system conditions.
5. An epidemiologist.
6. A medical staff to control epidemic diseases.
7. A pathologist with a sufficient experience to investigate samples taken from heart membranes and muscle.
8. A Psychologist

### **3. Requirements of support medical departments:**

The support medical departments of a hospital shall fulfill the following technical requirements:

- A. A laboratory: equipped with equipment for all types of routine tests required to assess patient before and after heart transplantation in addition to tissue analysis equipment, titration of cytotoxic antibodies, titration of medication levels including cyclosporine and alikes thereof as well as various immunological tests.
- B. Medical imaging: either via ordinary x-rays, radionuclides diagnosis, computed tomography (CT) and 2D echo devices.

### **4. Requirements of medications:**

The following medications shall always be available in a hospital:

- A. Immunosuppressants: calcineurin, azathioprine and prednisolone inhibitors, antimetabolites and rapamycin receptor inhibitor or alikes thereof.
- B. Medications used to treat seizures such as: methylprednisolone, anti-lymphocyte globulin (ALG), anti-thymocyte globulin (ATG) and monoclonal antibodies.
- C. Fluids used to hydrate muscles such as: urocoline, University of Wisconsin solution or HTK solution.
- D. Medications used to treat bacterial, viral, parasitic and fungal infections.

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### **Third: Lungs Transplantation**

#### **1. Requirements of technical team:**

The technical team shall be made up of the following:

A. Lungs transplantation consultants: with a sufficient experience in the field of lungs transplantation working for one of the internationally recognized surgical centers. A lungs transplantation consultant should have performed a sufficient number of lungs transplantation operations.

B. Intensive care unit specialists: with an experience in following up post-lungs surgery cases, preferably with previous experience in following up lungs transplantation cases.

C. Pulmonologists with a capacity to perform all tests associated with lung and examination thereof either via ordinary means or via advanced ones. Such pulmonologists shall have an experience in following up patients before and after transplantation operations with a competency of taking samples required.

D. A nursing staff: nurses shall be highly experienced in order to take care of patients during lungs transplantation operations and thereafter.

E. An organs transplantation coordinator

F. A social services specialist

G. A nutritionist

#### **2. Requirements of technical preparations:**

The hospital shall be technically equipped with the following:

A. Technical departments:

A GIT department, a medical imaging department, a haematology department, a pathology department, a biological and chemical laboratory, a dialysis unit, an immunology department, a heart diseases department and a heart surgery department.

B. A fully equipped room; set for lungs surgeries.

C. An intensive care unit (ICU) with availability of isolating patients whenever necessary.

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D. Availability of the following specialists:

1. A nephrologist with a sufficient experience to follow up organs transplantation cases.
2. An immune diseases specialist.
3. A cardiologist.
4. A physiotherapist to follow up the patient's respiratory system condition.
5. A medical staff to control epidemic diseases inside the hospital.
6. A pathologist with a sufficient experience to investigate samples taken from lungs tracheas and tissues.
7. A Psychologist to assess the patient's psychological condition before and after the transplantation.

### **3. Requirements of support medical departments:**

The support medical departments of a hospital shall fulfill the following technical requirements:

A. A laboratory: equipped with equipment for all types of routine tests required to assess patient before and after lungs transplantation in addition to tissue analysis equipment, titration of cytotoxic antibodies, titration of medication levels including cyclosporine and alikes thereof as well as various immunological tests.

B. Medical imaging: devices to image the lungs in order to facilitate the performance of all ordinary and advanced studies and tests such as (lungs computed tomography, radionuclides diagnosis, scintigraphy...etc).

### **4. Requirements of medications:**

The following medications shall always be available in a hospital:

A. Immunosuppressants: calcineurin, azathioprine and prednisolone inhibitors, antimetabolites and rapamycin receptor inhibitor or alikes thereof.

B. Medications used to treat seizures such as: methylprednisolone, anti-lymphocyte globulin (ALG), anti-thymocyte globulin (ATG) and monoclonal antibodies.

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C. Fluids used to hydrate muscles such as: urocoline, University of Wisconsin solution or HTK solution.

D. Medications used to treat bacterial, viral, parasitic and fungal infections.

#### **Fourth: Liver Transplantation**

##### **1. Requirements of technical team:**

The technical team shall be made up of the following:

A. Liver and bile ducts consultants: with an experience of not less than one year working for one of the internationally recognized liver transplantation centers.

B. A herpetologist with an experience of not less than one year working for one of the internationally recognized liver transplantation centers.

C. A Paediatric Gastroenterologist with an experience of not less than one year working for one of the internationally recognized liver transplantation centers.

D. An anaesthesiologist with an experience of not less than six months working for one of the internationally recognized liver transplantation centers.

E. An intensive care unit consultant.

F. A nutritionist

G. An epidemiologist

H. A liver transplantation coordinator

I. A nursing staff: nurses shall be highly experienced in order to take care of patients during liver transplantation and thereafter.

##### **2. Requirements of technical preparations:**

The hospital shall be technically equipped with the following:

A. Technical departments:

a heart diseases department, an endoscopy department, a medical imaging department, a haematology department, a pathology department, a biological and chemical laboratory, a dialysis unit, an intensive care unit (ICU), an immunology department, a pulmonology department, a physical therapy department and a microbiology department (germs, parasites, viruses and fungi)

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B. Two fully equipped rooms minimum; set for liver transplantation operations including in particular:

A thromboelastogram device, a blood purification device, a fast pumping device, a venous blood pump, a laser device to stop bleeding or any device of same category, a blood warmer with technicians to operate it.

### **3. Requirements of medical departments:**

The support medical departments of a hospital shall fulfill the following technical requirements:

A. A laboratory: equipped with equipment for all types of routine tests required to assess patient before and after liver transplantation in addition to tissue analysis equipment, titration of cytotoxic antibodies, titration of medication levels including cyclosporine and alikes thereof as well as various immunological tests.

B. Medical imaging: either via ordinary x-rays, ultrasound imaging (with availability of a movable device), Doppler, radionuclides diagnosis, computed tomography (CT) to image arteries and devices for imaging biliary ducts through skin.

C. The endoscopy department: shall contain all medical and diagnostic capabilities including a pancreas-imaging device and devices for imaging biliary ducts through ERCP.

### **4. Requirements of medications:**

The following medications shall always be available in a hospital:

A. Immunosuppressants: calcineurin, azathioprine and prednisolone inhibitors, antimetabolites and rapamycin receptor inhibitor or alikes thereof.

B. Medications used to treat seizures such as: methylprednisolone, anti-lymphocyte globulin (ALG), anti-thymocyte globulin (ATG) and monoclonal antibodies.

C. Fluids used to hydrate muscles such as: urocoline, University of Wisconsin solution or HTK solution.

D. Medications used to treat bacterial, viral, parasitic and fungal infections.

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## **Fifth: Pancreas Transplantation**

### **1. Requirements of technical team:**

The technical team shall be made up of the following:

- A. A pancreas transplantation consultant: with an experience of not less than one year working for one of the internationally recognized pancreas transplantation centers.
- B. A nephrologist with an experience of not less than one year working for one of the internationally recognized kidney transplantation centers.
- C. A diabetes consultant: at least one consultant of endocrinology and metabolism- with an experience of not less than one year working for one of the internationally recognized centers treating complicated cases of diabetes.
- D. A nursing staff: nurses shall be highly experienced in order to take care of patients during pancreas transplantation and thereafter.
- E. A pancreas transplantation coordinator: with sufficient experience to fulfil the said duties. It may be one of the said technical team members.
- F. A nutritionist
- G. A social services specialist

### **2. Requirements of technical preparations:**

The hospital shall be technically equipped with the following:

#### A. Technical departments:

a heart diseases and a cardiac catheterization department, a GIT department (with available endoscopes), pulmonary department (with available endoscopes), a medical imaging department, a haematology department, a tissues department, a biological and chemical laboratory, a dialysis unit (preferably equipped with movable devices and equipment) and an intensive care unit (ICU)

#### B. Two operation rooms (OR) minimum

C. Two rooms minimum for seated patients following pancreas transplantation operations.

The support medical departments of a hospital shall fulfill the following technical requirements:

A. A laboratory: equipped with equipment for all types of routine tests required to assess patient before and after pancreas transplantation including tissue, viruses and fungi analysis in addition to tissues analysis devices, titration of cytotoxic antibodies, titration of medication levels including cyclosporine and alikes thereof as well as various immunological tests.

B. Medical imaging: either via ordinary x-rays, ultrasound imaging, radionuclides diagnosis, computed tomography (CT) and interventional radiology.

The following medications shall always be available in a hospital:

A. Immunosuppressants: calcineurin, azathioprine and prednisolone inhibitors, antimetabolites and rapamycin receptor inhibitor or alikes thereof.

B. Medications used to treat seizures such as: methylprednisolone, anti-lymphocyte globulin (ALG), anti-thymocyte globulin (ATG) and monoclonal antibodies.

C. Fluids used to hydrate muscles such as: urocoline, University of Wisconsin solution or HTK solution.

D. Medications used to treat bacterial, viral, parasitic and fungal infections.

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The technical team shall consist of the following:

A. A corneal transplantation consultant: with an experience of not less than one year working in the field of corneal transplantation and external eye diseases for one of the internationally recognized corneal transplantation centers. The corneal transplantation consultant should have performed such operations previously in person and shall submit a certificate thereof. The corneal transplantation

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consultant should have gained at least a five-year experience transplanting corneal in one of the recognized hospital and shall submit a certificate from that hospital for which he has worked.

B. An anaesthesiologist with a former experience in the field of ocular anaesthesia.

C. A microbiologist available to work in the hospital with the availability of microbiology department (germs, parasites, viruses and fungi)

D. A technician working for the eye bank with an experience in the field of corneal preservation and assessment of corneal validity for transplantation. The corneal transplantation consultant may fulfil such duty.

E. A corneal transplantation coordinator with a sufficient experience to coordinate the process of corneal preservation until transplantation phase.

F. A nursing staff: nurses shall be highly experienced in order to take care of patients during corneal transplantation and thereafter.

## **2. Requirements of technical preparations:**

The hospital shall be technically equipped with the following:

A. An ophthalmology department: the department shall be fully equipped i.e. the following equipment shall be available:

1. Special biological microscopes (Slit Lamp)
2. Fundusscopes
3. Snellen charts
4. Topography tests to measure the curvature of the cornea
5. A refractometer
6. Eye pressure measuring devices
7. Fully equipped operation rooms (ORs) set for corneal transplantation procedures such as: surgical microscopes, vitrectomy units, etc.

B. The hospital outpatient clinics shall contain all equipment required to examine the eyes of patients, who went under a surgery or are scheduled for corneal

transplantation. Such equipment include special forceps, scalpels, eyelid retractors, etc.