

Cabinet Resolution No. (25) of 2020 on the Executive Regulation of Decree-Federal Law No. (5) of 2016 on the Regulation of Human Organs and Tissue Transplantation

The Cabinet:

- Upon reviewing the Constitution;
- Federal Law No. 1 of 1972 concerning the Competences of the Ministries and the Powers of the Ministers, as amended; Federal Decree-Law No. 5 of 2016 On the Regulation of Human Organs and Tissue Transplantation;
- Based on the proposal of the Minister of Health and Prevention, and the approval of the Cabinet,

Has resolved:

Article (1)

Definitions

The definitions stated in the aforementioned Federal Decree-Law No. 5 of 2016 shall apply to this Resolution. Other than that, the following words and expressions shall have the meanings ascribed thereto unless the context requires otherwise:

- Ministry** : Ministry of Health and Prevention.
- Decree-Law** : Federal Decree-Law No. 5 of 2016 On the Regulation of Human Organs and Tissue Transplantation.

Article (2)

Requirements and Procedures to License Health Facilities

1. A health facility that desires to conduct human organs and tissues transplantation shall have the authorization to do so from the concerned health authority before starting any activity in this field.
2. In order to acquire the aforementioned authorization in Clause 1 of this Article, the health

facility shall have the necessary installations, accessories, human resources and infrastructure to exercise this activity in a way that is suitable to the field the facility desires to work in subject to conditions stipulated in the annex attached to this Resolution.

Article (3)

Requirements and Procedures for Physicians Authorizations

1. A physician who performs human organs, parts of organs and tissues transplant operation shall have a license from the concerned health authority before performing the operation.
2. In order to obtain the aforementioned license, the physician shall have the following:
 - a. He shall have an efficiency recognized by the health authority to perform human organs, parts of organs and tissues transplant operations based on his experience in this field or the suitable training he received, in addition to the kind of human organs or tissues that enter within the scope of his work and practice.
 - b. The physician shall sign an acknowledgement notifying that he/she has reviewed the applicable legislation of the State in the field of human organs and tissues and that he/she is committed to it.
 - c. Any other requirements or conditions the health authority provides.

Article (4)

Requirements to Renew the License of the Health Facility

In order to renew the license of the health facility, the following shall be available:

1. Requirements stipulated in Clause 2 of Article 2 of this Resolution shall be available.
2. A detailed scientific annual report shall be submitted to the Ministry showing the results of transplantation in the health facility according to the data determined by the Ministry, provided that the following shall be included:
 - a. The condition of patients for whom human organs, parts of organs and tissues transplant operations were performed.
 - b. The condition of the transplanted organ.
 - c. Percentage of implications due to transplantation compared to world criteria and

procedures that were taken in this respect.

3. Any other requirements determined by the health authority, provided that it includes the minimum number of operations the health facility has performed according to recognized medical fundamentals.

Article (5)

Exchange Transfer

The following shall be available to perform exchange transfer:

1. There shall be two patients who need to transplant a human organ or tissue and they are not relatives up to the fourth degree.
2. There is a donor from the part of each patient, provided that the donor is a relative up to the fourth degree.
3. Donors shall agree to donate in exchange for the other patient who is not a relative as mentioned.
4. Physicians shall admit that donation is viable from the medical respect for the benefit of the two patients reciprocally.
5. An undertaking and an acknowledgement from each donor shall be provided that they shall not claim any compensation regardless the outcome of the transplant operation.

Article (6)

Requirements to Prove Donation After Death

A person who desires to donate one of his organs, parts of organs or tissues after death shall prove this in his ID according to the rules and procedures organizing IDs, through registration at the website determined by the Ministry or to record this in a written will and two persons of full capacity shall sign it according to the template prepared by the Ministry.

The same provision shall be applicable to the person who does not desire to donate one of his organs, parts of organs or tissues after death. His desire shall be proved the same way as stated in the above paragraph of this Article.

In all cases, the desire to donate or not to donate may be amended without any restriction or

condition subject to the same procedures stipulated in this Article.

Article (7)

Register of Persons Desiring to Donate

A register shall be created at the Ministry to include the names of persons desiring to donate after death. This shall be through the data recorded at the Federal Authority for Identity and Citizenship or the website determined by the Ministry.

Article (8)

Amendment of License Requirements

Upon a resolution issued by the Minister and in coordination with health authorities, requirements stipulated in the annex of this Resolution may be amended without prejudice to the Decree-Law.

Article (9)

Issuance of Executive Resolutions

The Minister shall issue the resolutions necessary to implement the provisions of this Resolution.

Article (10)

Publication and Enforcement of the Resolution

This Resolution shall be published in the Official Gazette; and shall enter into force as of the day following the date of its publication.

Signed

Mohammed Bin Rashid Al Maktoum

Prime Minister

Issued by us:

Date: 7 Shaban 1441 H

Corresponding to: 31 March 2020

Annex

As attached to the Cabinet Resolution No. 25 of 2020 on the Executive Regulation of Decree-Federal Law No. 5 of 2016 on the Regulation of Human Organs and Tissue Transplantation

Requirements for Private Health Facilities Authorization to Perform Human Organs and Tissue Transplantation

First: Kidney Transplantation

1. Requirements of the Technical Staff:

The technical staff shall consist of:

- a. Consultant kidney transplant surgeon: provided that he has at least one year's experience from a recognized kidney transplant center.
- b. Consultant nephrologist: provided that he has at least one year's experience from a recognized kidney transplant center.
- c. Nursing staff: They should be well trained with high experience in taking care of patients during and after kidney transplantation.
- d. Kidney transplant coordinator: This individual must have an adequate experience in order to perform the previously mentioned duties. The coordinator can also be appointed from the above-mentioned staff.
- e. A dietitian.
- f. A social worker.

2. Requirements of technical facilities:

The hospital must have the following departments:

- a. The following technical departments:
- b. Cardiology Department, Digestive System Diseases Department, (Endoscopy is available), Chest Diseases Department (with endoscopy available), Medical Imaging Department, Hematology Department, Pathological Anatomy Department, Chemical and Biological Analysis Laboratory, Kidney and Hemodialysis Unit, (germs, parasites,

viruses and fungi) and Intensive Care Unit. At least two operations rooms must be available.

- c. At least two rooms for management of post-transplant patients.

3. Requirements of Departments of Support services:

Departments of support service at the hospital shall fulfil the its technical requirements as follows:

- a. Laboratory: All routine investigations necessary for the patients either before or after the transplantation must be available. Facilities to perform tissue typing, cytotoxic antibodies, and blood levels of drugs including cyclosporine or similar drugs should be available.
- b. Radiology: whether conventional X-ray, ultrasound, radioisotope scanning, and computerized axial tomography.

4. Drugs Requirements:

The following drugs must be continuously available in the hospital:

- a. Immunosuppressive drugs: calcineurin, azathioprine, prednisolone, anti-metabolites, and rapamycin receptor inhibitors or similar drugs.
- b. Drugs for treating rejection episodes such as: methylprednisolone, (ALG) or anti-thymocyte globulin, anti-thymus globulin and monoclonal antibodies (ATG).
- c. Solution for perfusing the organs such as Eurocollins solution or Wisconsin University solution or HTK solution.
- d. Drugs for treating bacterial, viral, fungal, or parasitic infections.

Second: Heart Transplantation

1. Requirements of the Technical Staff:

The technical staff shall consist of:

- a. Consultant cardiac transplant surgeons: They must have a good experience in performing open heart surgeries and are fully certified and experienced from one of

the recognized heart centers internationally, and have performed an adequate number of pump cases (more than 200).

- b. ICU specialists: They should have an adequate experience in follow-up of patients after open heart surgery and preferably having adequate experience in follow-up of cardiac transplant recipients.
- c. Consultants in cardiology: They should have an adequate experience to perform all relevant cardiac investigations, whether through conventional or advanced means, including endomyocardial biopsy and to follow-up pre-and post-heart transplant patients.
- d. Nursing staff: They should be well trained with high experience in taking care of patients during and after heart transplantation.
- e. Organs transplant coordinator.
- f. A social worker.
- g. A dietitian.

2. Requirements of technical facilities:

The hospital must have the following departments:

- a. The following technical departments:
- b. Departments of Gastroenterology, Radiology, Hematology, Pathology laboratory, Biochemical laboratory, Nephrology with hemodialysis unit, and Immunology. At least two fully equipped open-heart surgical theatres must be available.
- c. Circulatory support systems, such as intra-aortic balloon pump, by-pass support systems (CPR), or mechanical assist devices with the availability of technicians necessary to handle them.
- d. A fully equipped ICU should be available for management of patients after open-heart surgery with facilities to isolate patients as well as installation of pacemakers, both temporary and permanent.
- e. The following specialists shall be available:
 - 1. Fully certified nephrologist experienced in the follow-up of organ transplant

recipients.

2. Immunologists experienced in the follow-up of heart transplant recipients.
3. Pulmonologist.
4. Certified respiratory therapist.
5. Infectious disease specialist.
6. Medical team for infection control at the hospital.
7. Certified pathologists with sufficient experience in interpreting myocardial biopsies.
8. Certified psychiatrist.

3. Requirements of Departments of Support services:

Departments of support service at the hospital shall fulfil its technical requirements as follows:

- a. The laboratory: It shall have all regular test equipment required to assess patients before and after transplanting in addition tissue culture devices, calibration of Cytotoxic antibodies, level calibration of difference medicines, including Cyclosporine or alike and different immunity tests.
- b. Radiology: Conventional X-ray, ultrasound, radioisotope scanning, and computerized axial tomography. There should be availability of bimodal echocardiography.

4. Drugs Requirements:

The following drugs must be continuously available in the hospital:

- a. Immunosuppressive drugs: calcineurin, azathioprine, prednisolone, anti-metabolites, and rapamycin receptor inhibitors or similar drugs.
- b. Drugs for treating rejection episodes such as: methylprednisolone, (ALG) or anti-thymocyte globulin, anti-thymus globulin and monoclonal antibodies (ATG).
- c. Solution for perfusing the organs such as Eurocollins solution or Wisconsin University solution or HTK solution.
- d. Drugs for treating bacterial, viral, fungal, or parasitic infections.

Third: Lung Transplantation

1. Requirements of the Technical Staff:

The technical staff shall consist of:

- a. Consultant lung transplant surgeons: They must have a good experience in performing open lung surgeries and are fully certified and experienced from one of the recognized lung centers internationally, and have performed an adequate number of lung transplantation.
- b. ICU specialists: They should have an adequate experience in follow-up of patients after open lung surgery and preferably having adequate experience in follow-up of lung transplant recipients.
- c. Consultants in chest medicine: They should have an adequate experience to perform all lung investigations, whether through conventional or advanced means, including lung biopsy and to follow-up pre-and post-lung transplant patients.
- d. Nursing staff: They should be well trained with high experience in taking care of patients during and after lung transplantation.
- e. Organs transplant coordinator.
- f. A social worker.
- g. A dietitian.

2. Requirements of technical facilities:

The hospital must have the following departments:

- a. The following technical departments:
- b. Departments of Gastroenterology, Radiology, Hematology, Pathology laboratory, Biochemical laboratory, Nephrology with hemodialysis unit, Immunology, Cardiology and Cardiac surgery. A fully-equipped lung transplantation theatre.
- c. ICU with isolation possibilities if the patient condition requires this.
- d. The following specialists shall be available:
 1. Fully certified nephrologist experienced in the follow-up of organ transplant recipients.
 2. An immunologist.

3. A cardiologist.
4. Certified respiratory therapist.
5. Medical team for infection control at the hospital.
6. A pathologist with sufficient experience in interpreting lung biopsies.
7. A psychiatrist to evaluate patients before and after transplantation.

3. Requirements of Departments of Support services:

Departments of support service at the hospital shall fulfil the its technical requirements as follows:

- a. The laboratory: It shall have all regular test equipment required to assess patients before and after transplanting in addition tissue culture devices, calibration of Cytotoxic antibodies, level calibration of difference medicines, including Cyclosporine or alike and different immunity tests.
- b. Radiology: X-ray facilities for conventional and advanced lung investigations (e.g., CT scan, radioisotope scanning...etc.).

4. Drugs Requirements:

The following drugs must be continuously available in the hospital:

- a. Immunosuppressive drugs: calcineurin, azathioprine, prednisolone, anti-metabolites, and rapamycin receptor inhibitors or similar drugs.
- b. Drugs for treating rejection episodes such as: methylprednisolone, (ALG) or anti-thymocyte globulin, anti-thymus globulin and monoclonal antibodies (ATG).
- c. Solution for perfusing the organs such as Eurocollins solution or Wisconsin University solution or HTK solution.
- d. Drugs for treating bacterial, viral, fungal, or parasitic infections.

Fourth: Liver Transplantation

1. Requirements of the Technical Staff:

The technical staff shall consist of:

- a. Consultants in liver transplantation: They should have at least one year of experience in hepatobiliary surgery from a recognized liver transplant center internationally.
- b. Hepatologist: A hepatologist with a minimum of one year's experience from a recognized liver transplant center internationally.
- c. Pediatric gastroenterologist: with a minimum of one year's experience from a recognized liver transplant center internationally.
- d. Anesthesia consultant: an anesthesia consultant with a minimum of one year's experience from a recognized liver transplant center internationally.
- e. Intensive Care Consultant.
- f. A dietitian.
- g. An infectious disease consultant.
- h. Liver transplant coordinator.
- i. Nursing staff: They should be well trained with high experience in taking care of patients during and after liver transplantation.

2. Requirements of technical facilities:

The hospital must have the following departments:

- a. The following technical departments:
- b. Cardiology, Endoscopy, Radiology, Hematology and blood bank, Pathology, Biochemistry laboratory, Nephrology with hemodialysis unit, ICU facility, Immunology, Chest diseases, Psychiatry, Physio-therapy, Microbiology laboratory (germs, parasites, viruses and fungi).
At least two fully-equipped operating theatres containing all the necessary equipment for liver transplantation, specifically the following:

Thromboelastogram, Cell saver machine, Rapid infusion system, Venevenous by-pass machine, Infra-red coagulator or equivalent, Blood warmer, Technicians needed to operate these machines should be available.

3. Requirements of Departments of Support services:

Departments of support service at the hospital shall fulfil the its technical requirements as follows:

- a. The laboratory: It shall have all routine laboratory services, including pre- and post-

transplant work-up in addition to HLA typing, cytotoxic antibodies, drug levels of cyclosporine and similar drugs.

- b. Radiology: whether conventional X-ray facility, ultrasound (with the availability of a portable machine), Doppler ultrasonography, isotope scan, CT scan, and percutaneous transhepatic cholangiography.
- c. Endoscopy department: This department should have all diagnostic and therapeutic facilities, including Endoscopic Retrograde Cholangio Pancreatography (ERCP).

4. Drugs Requirements:

The following drugs must be continuously available in the hospital:

- a. Immunosuppressive drugs: calcineurin, azathioprine, prednisolone, anti-metabolites, and rapamycin receptor inhibitors or similar drugs.
- b. Drugs for treating rejection episodes such as: methylprednisolone, (ALG) or anti-thymocyte globulin, anti-thymus globulin and monoclonal antibodies (ATG).
- c. Solution for perfusing the organs such as Eurocollins solution or Wisconsin University solution or HTK solution.
- d. Drugs for treating bacterial, fungal, or parasitic infections.

Fifth: Pancreas Transplantation

1. Requirements of the Technical Staff:

The technical staff shall consist of:

- a. A consultant pancreas transplant surgeon: A consultant in the field of pancreas transplantation, with at least one year experience in an internationally recognized center for pancreas transplantation.
- b. Consultant nephrologist: with at least one year's experience from an internationally recognized kidney transplant center.
- c. A diabetologist: There should be at least one diabetologist consultant with at least one year experience in an international recognized center for treating complicated diabetic cases.

- d. Nursing staff: They should be well trained with high experience in taking care of patients during and after transplantation.
- e. Pancreas transplant coordinator: This individual must have an adequate experience in order to perform coordination duties. The coordinator can also be appointed from the above-mentioned staff.
- f. A dietitian.
- g. A social worker.

2. Requirements of technical facilities:

The hospital must have the following departments:

- a. The following technical departments:
- b. Cardiology and Angioplasty Department, Digestive System Diseases Department, (Endoscopy is available), Chest Diseases Department (with endoscopy available), Medical Imaging Department, Hematology Department, Tissues Department, Chemical and Biological Analysis Laboratory, Kidney and Hemodialysis Unit, (germs, parasites, viruses and fungi) and Intensive Care Unit. At least two surgical operations rooms must be available.
- c. At least two rooms for management of post-transplant patients.

3. Requirements of Departments of Support services:

Departments of support service at the hospital shall fulfil its technical requirements as follows:

- a. The laboratory: It shall have all routine laboratory test equipment required to assess patients before and after transplant, including bacterial, viral and fungal infections, in addition to HLA typing, cytotoxic antibodies, drug levels of cyclosporine and similar drugs.
- b. Radiology: whether conventional X-ray, ultrasound, radioisotope scanning, computerized axial tomography and interventional radiology.

4. Drugs Requirements:

The following drugs must be continuously available in the hospital:

- a. Immunosuppressive drugs: calcineurin, azathioprine, prednisolone, anti-metabolites, and rapamycin receptor inhibitors or similar drugs.
- b. Drugs for treating rejection episodes such as: methylprednisolone, (ALG) or anti-thymocyte globulin, anti-thymus globulin and monoclonal antibodies (ATG).
- c. Solution for perfusing the organs such as Wisconsin University solution or HTK solution.
- d. Drugs for treating bacterial, viral, fungal, or parasitic infections.

Sixth: Corneal Transplantation

1. Requirements of the Technical Staff:

The technical staff shall consist of:

- a. Consultant corneal transplant surgeon: There should one consultant in corneal transplantation with good experience in performing corneal transplant and treating external eye diseases for at least one year from a recognized international corneal transplant center, provided that he has done such kind of operations himself within this period, with a certificate confirming that experience. Alternatively, he should have a certificate of experience of at least five years in corneal transplantation from a recognized hospital provided that he provides this certificate from the same hospital he worked for.
- b. A consultant anesthesiologist with a previous experience in anesthesia for eye surgery.
- c. A full-time microbiologist working for the hospital, with Microbiology laboratory Department (germs, parasites, viruses and fungi).
- d. An eye-bank technician with experience in preservation of corneas and evaluation of suitability of corneas for transplantation. Alternatively, the consultant corneal transplant surgeon can perform this duty.
- e. A corneal transplant coordinator with experience in coordination of corneal transplantation and preservation of corneas until the time of transplant.

- f. Nursing staff: They should be well trained with high experience in taking care of patients during and after corneal transplantation.

2. Requirements of technical facilities:

The hospital must have the following departments:

- a. Ophthalmology department fully equipped with necessary medical equipment, specifically:
 - 1. Bio-microscopes (slit lamp)
 - 2. Ophthalmoscopes.
 - 3. Visual acuity charts.
 - 4. Refractometer.
 - 5. Retinoscopes.
 - 6. Tonometers.
 - 7. Fully equipped operating rooms for corneal transplant operations such as a surgical microscope and vitrectomy equipment.
- a. Outpatient clinics shall be fully equipped for examination of patients who have already undergone corneal transplantation as well as evaluating those who are potential candidates (such as have special forceps, blades, eyelid retractor, etc.).