

**Cabinet Resolution No. (40) of 2019**  
**Concerning the Executive Regulations of Federal Decree-Law**  
**No. (40) of 2016 Concerning Medical Liability**

**The Cabinet,**

- Having Reviewed the Constitution; and
- Federal Law No. (1) of 1972 on the Competencies of Ministries and Powers of Ministers, as amended; and
- Federal Decree-Law No. (4) of 2016 on Medical Liability; and
- Cabinet Resolution No. (33) of 2009 on the Executive Regulations of Federal Law No. (10) of 2008 on Medical Liability; and
- Cabinet Resolution No. (6) of 2012 on the Supreme Committee for Medical Liability; and
- Based on the Proposal submitted by Minister of Health and Prevention, and the Cabinet approval.

**Hereby resolves the following:**

**Article (1)**

The same meanings provided for in the above-referenced Federal Decree-Law No. (4) of 2016 shall apply to this Resolution. Other than that, the following terms and expressions shall have the meanings assigned thereto respectively, unless the context otherwise requires:

- |                          |   |
|--------------------------|---|
| <b>Committee</b>         | : The Medical Liability Committee provided for in the Decree-Law.             |
| <b>Supreme Committee</b> | : The Supreme Committee for Medical Liability provided for in the Decree-Law. |
| <b>Decree-Law</b>        | : The Federal Decree-Law No. (4) of 2016 Concerning Medical Liability.        |

## **Article (2)**

Without prejudice to the duties provided for in the Decree-Law, whoever practices the profession shall, within his / her sphere of competence, comply with the rules set out below that are in line with the nature of his /her work, as follows:

1. To perform his / her work in strict compliance with the principles of professional practice in general, and with the scientific and practical principles of the specialization practiced in particular, in accordance with the Protocols and Rules approved by the Health Authority.
2. To exercise utmost care for providing and following up on the health service vigilantly and watchfully, in accordance with the standard of practice of his/her average colleagues in terms of experience and qualification, and to carefully review the patient's medical history, unless he / she fails to do the same for circumstances beyond his / her control or due to the patient's own act.
3. Not to take advantage of the patient's need in order to achieve an unlawful benefit either for himself / herself or for Third Parties. Unlawful benefit includes any financial, in-kind, or moral gain that could not have been obtained without the patient's need for treatment. The pay received by the Professional Practitioner for his / her work duties shall not be covered by this provision.
4. Not to discriminate between patients or colleagues on the basis of Religion, Ethnicity, Social Standing, Gender or Nationality.
5. To document in the patient's medical file each action taken, including its type, date, and time.
6. To keep the patient, or anybody whose consent is required in accordance with Article (3) hereof, as the case may be, well informed of all complications that may result from the diagnosis or treatment in a clear and simplified manner.

## **Article (3)**

Without prejudice to the provisions of the Decree-Law, surgical operations may be performed only after taking into account the following:

1. The Health Facility at which the Surgery is to be performed shall be adequately equipped in line with the type of surgery, in terms of the medical and nursing staff, medical equipment and supplies necessary in terms of quality and safety, and all matters necessary for conducting such surgery and properly dealing with any complications or other potential repercussions.
2. To make an insightful assessment of the medical condition through necessary diagnostic checks, so as to ensure that the patient's health condition allows the surgical operation to be conducted.
3. To obtain a written consent after keeping the patient, or anybody whose consent is required, well informed of the nature of the surgery, the success ratio, and the potential complications, in the following manner:
  - a. From the patient himself / herself, if fully capacitated.
  - b. From the patient's spouse or a blood relative up to the fourth degree in accordance with paragraph (C) of this Clause, if the patient is of majority age, but his/her consent cannot be obtained for whatever reason, including:
    - Unconsciousness.
    - Loss of perception due to mental or psychological disease.
    - The health condition of the patient does not allow his/her consent to be obtained.
  - c. From the patient's spouse or a relative up to the fourth degree, if the patient is temporarily or permanently incapacitated, and the order of relatives shall be observed as much as possible. If there are conflicting opinions between relatives of the same degree, those expressing the affirmative opinion for consent shall have the prevailing opinion, if the same is in the best interest of the patient according to the discretion of the treating doctor and some other doctor.
4. The rules and procedures provided for in this Article shall apply to the treatment cases of special nature, including:
  - a. Chemotherapy.

- b. Radiotherapy.
- c. Any other therapy named by the Minister in coordination with the competent Health Authorities.

#### **Article (4)**

1. It shall be prohibited to allow medical research or experiments to be conducted on any person without obtaining his/her consent and a written permission from the competent authority named by a decision of the Minister in coordination with the Health Authorities beforehand.
2. The Minister shall, after coordination is made with the Health Authorities, issue a Resolution on the controls, rules and procedures regulating the conducting of medical research and experiments on humans.

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

1. The medical malpractice shall be deemed of a gross nature if it leads to the death of the patient or fetus, eradication of a human organ by mistake, loss of organ function, or any other serious damage, in addition to the availability of any of the following criteria from which the medical malpractice results:
  - a. Unpardonable unfamiliarity with the well-established medical standards according to the level and specialization of professional practitioner.
  - b. Adopting a medically unrecognized method.
  - c. Unjustified deviation from medical standards and rules for practicing the profession.
  - d. The doctor is under the influence of alcohol, drugs, or psychotropic substances.
  - e. Gross negligence or clear lack of perception upon taking well-established medical actions; e.g. leaving medical equipment in the patient's body, giving him/her an overdose of medicine, failure to operate a medical device during or after the surgical operations, resuscitation or childbirth, failure to

- give the patient medically appropriate medicine, or any other act classified as gross negligence.
- f. Practicing the profession deliberately beyond the scope of specialization or clinical privileges conferred upon the doctor under the professional license.
  - g. The doctor's use of diagnostic or therapeutic means, with no prior practice or training, and without medical supervision.
2. The Committee and the Supreme Committee, each within the area of its competence, shall consider the complaints and grievances relating to the medical malpractice, and determine the following:
- a. The criterion relied upon to classify the occurring medical malpractice of gross nature.
  - b. Identifying the elements contained in the file and confirming the existence of a gross medical malpractice.
  - c. Identifying the type of damage and error.

### **Article (6)**

The Professional Practitioner shall furnish to the Health Authority any data or information about the patient, which has come to his/her knowledge during or on account of practicing the profession or as obtained from the patient, in accordance with the following controls and conditions:

1. There must be a written request from the Health Authority, and the purpose of providing such data and information is to protect the public health.
2. The data and information required to be disclosed shall be precisely specified.
3. The data and information required to be disclosed shall be necessary for carrying out an action or program falling within the work scope of the Health Authority.
4. Such data and information may be used solely for the purpose specified in the letter of the Health Authority.
5. Such data and information may not be handled by non-specialists.
6. The reputation of the patient or his / her family may not be tainted.

## **Article (7)**

Health Authorities may establish a system for the provision of Telehealth Services, in accordance with the terms and conditions set forth in the annex attached herewith.

## **Article (8)**

1. The competent Health Authority shall receive the complaints relating to the medical malpractice. The complaints shall be filed in accordance with the following procedures:
  - a. To be submitted in a paper or an electronic format.
  - b. To be written out in Arabic, but if written in any other language, it shall be accompanied by translation into Arabic.
  - c. The complaint's subject must be precisely stated.
  - d. To be accompanied by all documents related thereto, if possible.
  - e. To be containing the detailed information about the complainant and patient or his/her legal representative, if any, in particular, the personal address and any other data that facilitate communication with him/her.
2. The complainant may amend or withdraw his / her complaint or add any other documents before the committee's report is issued.
3. The Court or the Public Prosecution shall turn over the lawsuits or complaints submitted thereto on the medical malpractice, together with a copy of their attachments, to the competent Health Authority, in order to be submitted to the Committee and satisfy all procedures related thereto.

The Health Authority shall, in all cases, turn over the complaints received by it to its affiliated committee, so that the latter shall take the appropriate action and exercise the competencies vested therein in accordance with the applicable legislation.

## **Article (9)**

1. A Committee to be known as (Medical Liability Committee) shall be composed at each Health Authority, by virtue of a resolution by the Minister or the Head of the Health Authority, as the case may be. Members of such shall include doctors specializing in the specializations named by the Health Authority. The resolution issued in this regard shall name the committee's chairman, deputy chairman, members, Rapporteur, and the term of membership.
2. The Committee may solicit the opinion of one or more doctors from other specializations, or the opinion of any person at its discretion, depending on the nature of the case under consideration. The committee may also compose one or more technical committees that have specialist doctors, in order to rely upon their opinion on the file, without having a counted vote in the committee's resolution.
3. The Health Authority shall assign or establish an organizational unit to complete the administrative duties relating to the work of the committee.

## **Article (10)**

The Committee's Rapporteur shall carry out the following competencies:

1. Receiving the applications for referral to the Committee and record the same in the relevant records.
2. Requesting the original medical file and the documents and papers related to the case referred to the committee.
3. Calling the interested parties and anybody whose testimony is deemed necessary to be heard by the Committee.
4. Calling the members to meetings in coordination with the Committee's Chairman.
5. Drafting the Committee's agenda in coordination with the Committee's Chairman.
6. Drawing up the Committee's Minutes of Meetings.
7. Drawing up the Committee's final report after being signed by all members present and sending the same to the Health Authority.
8. Any other tasks assigned by the Committee's Chairman.

### **Article (11)**

1. The Committee shall convene at the call of its chairman or the deputy chairman in the absence of the chairman, to consider the cases referred thereto.
2. The quorum of the committee meeting shall be valid only if attended by two-thirds of the members, including the chairman or deputy chairman. The opinion of the committee shall be passed by the majority of votes the members present. In case of equal votes, the chairman of the meeting shall have the casting vote. If the medical malpractice is categorized as a gross one, the consent of two-thirds of the members present shall be a must.

### **Article (12)**

1. It is prohibited for any member of the Committee to attend its meetings or to give opinion on any matter referred thereto, in any of the following cases:
  - a. If he/she has a kinship relationship with either of the parties to the complaint up to the fourth degree.
  - b. If he/she is working under the management or supervision of either party to the complaint.
  - c. If he/she has previously treated the patient from the same disease under consideration in the complaint.
  - d. If the Complainee has previously consulted him / her about the medical condition subject of the complaint.
  - e. If there is any other relationship that constitutes a conflict of interest and raises doubts about the principle of neutrality.
2. The prohibition provided for in Paragraph (1) of this Article shall apply to anybody whose assistance is sought by the Committee for performing its functions.

### **Article (13)**

The provisions on experts shall also apply to the members of the Committee, in a manner that does not contradict the provisions of the Decree-Law. Each of them shall take the legal oath once before an Appeal Chamber within whose jurisdiction his/her



place of residence or the Committee's headquarters is located, before taking over his/her post in the Committee.

### **Article (14)**

The Committee shall submit an annual report on its activity to the competent Health Authority. The committee shall also be subject to the annual assessment of its work by the same Health Authority.

### **Article (15)**

The Health Authority shall hand over a copy of the committee's report to the parties to the complaint, by any of the following means:

1. By personal delivery, provided that the recipient shall sign in acknowledgment of receipt, with mention of the date of receipt and capacity of the recipient.
2. By ordinary mail or the registered letter with receipt acknowledgment requested.
3. By fax or e-mail if either is available at the Health Authority.

### **Article (16)**

1. Any entity conducting an investigation with the Professional Practitioner on merits relating to his / her work shall notify the Undersecretary or the Responsible Director at the Health Authority issuing the license, as the case may be, before the start of the investigation. Such notification shall take effect by virtue of an official letter containing the full name of the Professional Practitioner and his / her Employer, and the subject of investigation.
2. The Health Authority, to which the Professional Practitioner with whom the investigation is being conducted affiliates, may delegate one of its employees or one of the employees of the Professional Practitioner's Employer to attend the investigation sessions. It may also submit any documents or memoranda deemed necessary to the Investigating Body.
3. In all cases, the Investigating Body shall notify the Health Authority concerned of the findings of investigation immediately upon its completion.

## **Article (17)**

It shall be prohibited for any person to practice the profession in the absence of insurance against civil liability for medical malpractice and the risks arising from or due to the practice of the profession. Such insurance shall be provided by an insurance company duly licensed in the State. Health Facilities shall provide insurance for the professional Practitioner before allowing him / her to take over his / her post, and shall get the same renewed upon expiry.

## **Article (18)**

Without prejudice to the provisions of the Decree-Law and of civil and criminal liabilities, and unless otherwise stipulated in the legislation relating to the disciplinary regulations of the Health Authority, disciplinary penalties shall apply to any act in violation of the provisions hereof, in accordance with the following laws:

1. For private health facilities, disciplinary penalties provided in the Federal Law No. (4) of 2015 Concerning the Private Health Facilities, shall apply.
2. For professional practitioners at the private health facilities; most precisely doctors, disciplinary penalties provided in the Federal Law No. (5) of 2019 concerning the Practice of Human Medicine, shall apply.
3. For professional practitioners at private health facilities, other than doctors and pharmacists, disciplinary penalties provided for in the Federal Law No. (5) of 1984 Regarding the practice of some medical professions by pharmacists and non-physicians, shall apply.
4. For pharmacists and assistant pharmacists, the provisions of Federal Law No. (4) of 1983 concerning the Profession of Pharmacy and Pharmaceutical Institutions, shall apply.
5. For the professional practitioners at the Health Authorities, disciplinary penalties prescribed by such authorities shall be applied in a manner that does not contradict the provisions of the Decree-Law and this Resolution.

6. As for Professional Practitioners at the Federal Government, the provisions of Federal Decree-Law No. (11) of 2008 on Human Resources in the Federal Government, shall apply.

### **Article (19)**

The Cabinet Resolution No. (33) of 2009 on the Executive Regulations of Federal Law No. (10) of 2008 on Medical Liability, along with any provision that goes against or contradicts the provisions hereof, shall all be repealed.

### **Article (20)**

The Minister shall issue the resolutions required for enforcing the provisions hereof.

### **Article (21)**

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

**Mohammed Bin Rashid Al Maktoum**

**Prime Minister**

**Issued by us:**

**On: 29 Shawwal 1440 AH**

**Corresponding to: 2 July 2019**

**Annex attached to Cabinet Resolution No. (40) of 2019  
Concerning the Executive Regulations of the Federal Decree-Law No.  
(4) of 2016 Concerning Medical Liability**

**Rules & Conditions for Providing Telehealth services**

**First: Definitions**

**Remote Medical Consultation:** A type of medical consultation provided by means of information and communication technologies, to give advice on the best ways to deal with the health case and takes place between a doctor and another doctor or a doctor and a patient, in cases where the doctor and the patient do not exist at the same place.

**Remote Prescription:** When the competent doctor prescribes medications, in cases where the doctor and the patient do not exist at the same place, by means of information and communication technologies, after a remote diagnosis is conducted and without clinical examination of the patient, or remote prescription of medication based on a diagnosis made through the conventional clinical manner.

**Remote Diagnostics:** Identifying the nature of the disease or health case of the patient, through the use of information and communication technologies by the health service provider.

**Remote Patient Monitoring [RPM]:** Obtaining vital signs and monitoring the patient's condition, through the use of information and communication technologies by the health service provider.

**Remote Medical Intervention:** Any remote medical intervention action through the use of information and communication technologies.

## Second: Rules and Conditions for Providing Telehealth Services

- **General Rules:** They apply to all areas of providing telehealth services.
  1. Rules relating to the Facility that provides telehealth services:

The facility providing telehealth services shall abide by the following:

    - a. Obtain a license from the Health Authority allowing it to provide such services.
    - b. Provide a well-rounded technical network that ensures the proper provision of telehealth service, according to the standards set by the Health Authority.
    - c. Provide an adequate bandwidth.
    - d. Provide alternative ways for communication between the service provider and recipient.
    - e. Provide a backup power supply system.
    - f. Provide Servers within the State to store and record the information and a backup.
    - g. Provide cutting-edge internet technologies and systems that satisfy the requirements of the providing telehealth services.
    - h. Comply with high quality standards regarding telephone and call recording systems.
    - i. Provide the necessary technical equipment to register and document the healthcare service remotely provided.
    - j. Provide high-caliber qualified human resources to provide telehealth service, by making them undergo a special training that is in line with the nature of remotely provided healthcare service, including training on technical, technological and legal aspects as determined by the Health Authority in this regard.
    - k. Provide an insurance coverage for medical malpractice arising from or due to the provision of such service.
    - l. The working system adopted by the Facility shall satisfy the following requirements:

- 1) Provide evidence on the existence of a system for monitoring, overseeing and reporting the quality and safety of performance measures.
- 2) Provide the necessary means to maintain and document full records and data of persons receiving the telehealth service.
- 3) Provide a system to protect the data and records of the telehealth service, and allow only the authorized persons to access thereto.
- 4) Provide the necessary mechanisms to protect the privacy of persons receiving the telehealth service.
- 5) Develop a system to maintain the confidentiality of patients' files.
- 6) Develop manuals and procedures to regulate the provision of telehealth services, defining the roles and responsibilities within a governance system.
- 7) Develop a system for identifying the person receiving the telehealth service, and the necessary relevant documents as determined by the Health Authority.
- 8) Rules relating to Service Recipient:

Telehealth service recipients shall abide by the following instructions:

- m. Give consent to audio, video and other forms of recording.
- n. Agree to receive the service.
- o. Introduce himself /herself and give correct and complete information.

- **Special Rules:** They are the rules relating to each of the healthcare services remotely provided, on a case-by-case basis, according to the following:
  1. Rules on Remote Diagnostics Service:
    - a. The service shall be provided after an agreement is concluded between the service applicant and service provider, defining the procedures and methods of dealing between the two parties in this respect.
    - b. The following patient safety rules shall be observed:

- 1) The service must be provided by a diagnostic center duly licensed in the State.
- 2) Enable the Service Provide to access to the patient's previous medical images and related reports, for the sake of achieving accurate diagnosis and drawing up the necessary report.
- 3) Enable the Service Provider to obtain all correct patient-related data before its report is drawn up.
- 4) Easy communication with the doctor who drew up the remote diagnosis report, through the phone or any other means of communication available, so as to discuss the report whenever needed.

c. The following rules on the exchange of data and reports shall be observed:

- 1) Obtaining the patient consent before referring his / her data to any other Medical Facility for the sake of conducting remote diagnosis.
- 2) Referral of the data shall be made within the limits required by the patient's health case, and in a manner that ensures the completion of remote diagnosis as optimally as possible.
- 3) Establish precise procedures on how to transfer, archive, store, protect and maintain the confidentiality of the patient's data.

## 2. Rules on Remote Consultation Service:

Remote consultation shall be subjected to the relevant rules established by the Health Authority. In all cases, the health professional who deals directly with the patient shall be responsible for any healthcare work provided to the patient.

## 3. Rules related to Remote Prescription:

- a. Medications shall be remotely prescribed by a doctor duly licensed by the Health Authorities in the State and working at a Health Facility duly licensed to provide telehealth services.

- b. The doctor who remotely prescribes the medications shall examine the patient electronically, using e-technology, while adhering to the relevant standards for the level of healthcare within the State.
- c. Files and documents shall be documented in accordance with applicable rules and regulations.
- d. The prescription of medications shall be the result of a diagnosis that ensures that there are no impediments to prescribing and receiving the medications. It is also important to ensure that the patient is able to understand the risks and is well-aware of the benefits associated with the medication; otherwise, the patient should be referred to a healthcare doctor for clinical examination.
- e. The doctor shall discuss the treatment plan with the patient, unless the latter's physical or mental condition so prevents.
- f. Medications shall be prescribed in accordance with the applicable legislation in the State.
- g. The doctor may prescribe the medications without adhering to the remote prescription rules related to the diagnosis, and discuss the medications with the patient in the following cases:
  - 1) If consultation is made with another doctor having direct relationship with the patient, while providing continuing supervision of the treatment.
  - 2) Work shift case or by telephone coverage, so that the doctor who prescribes the medication has reviewed the patient's health records.

#### 4. Rules on Telehealth Monitoring:

- a. Submitting a complete application to install and activate the Telehealth Monitoring Service at the home or the place where the patient (the client) exists.
- b. Submitting a Telehealth Monitoring Service application or order signed and dated by the treating doctor of the patient (client).



- c. Ensuring that the Telehealth Monitoring data are collected reliably and accurately.
- d. Data shall be stamped with the date and time to protect them from alteration.
- e. Ensuring that the monitoring data are documented in the patient's electronic medical records (EMR).
- f. The patient's clinical data may not be re-monitored by any other service provider.
- g. Maintaining the system documents and use of information.
- h. The data shall be reviewed by the nurse or the assistant doctor, and each of them shall be responsible for reporting the data to the doctor, and the latter shall issue the prescriptions.
- i. Submitting the periodic reports on the patient's data to the doctor.
- j. The patient shall be entitled to suspend the Telehealth Monitoring Service from home at any time.
- k. Telehealth monitoring service providers shall be available around the clock.
- l. The Telehealth Monitoring service includes the number of times, the type of monitoring, the timing and method of obtaining and transferring the data (e.g., are the results of the blood glucose check are uploaded on daily, weekly basis or immediately.....?).
- m. Determining the time of expected response to the patient's data.
- n. Determining off-working hours coverage policy for uploading the data and using the automated alarm system.
- o. Actions for dealing with "undesirable events" shall be established and made available to the persons concerned.
- p. The monitoring standards for manual and electronic analysis shall be provided both separately and jointly.
- q. Ensuring that all Telehealth Monitoring devices are functioning properly.

- r. Sensors may not cause any damage or irritation to the patient's skin, nor cause sleep distress or form a risk if swallowed.
  - s. Establishing the protocols of response to alarms received from the Telehealth Monitoring system.
  - t. Providing and maintaining Telehealth Monitoring equipment, which is the responsibility of the homecare provider or hospital.
5. Rules relating to Remote Medical Intervention:
- a. Remote medical intervention is subject to the relevant rules established by the Health Authority.
  - b. In all cases, there must be a health professional alongside the patient, who is able to intervene whenever needed in case of malfunctioning of remotely operated technical devices.