

LAW OF PRIVATE HEALTH INSTITUTIONS

Issued under the Royal Decree No. M/40 dated 1423/11/03H and its Implementing Regulations issued by the Ministerial Resolution No. 1019377 dated 1439/05/28H.

Article (1)

The following words and expressions – wherever mentioned herein – shall have the meanings stated below, unless the context requires otherwise.

- **Private Health Institution: a health institution owned by the private sector and prepared for treatment, diagnosis, nursing, medical analysis or rehabilitation, or for the accommodation of convalescents. It shall include the following:**
 1. Hospital: a facility where patients are received, examined, treated, and hospitalized.
 2. General Polyclinic: a facility where patients are received, examined, and treated. It shall have at least three different medical specialties, one of which is a primary specialty (surgery, internal medicine, obstetrics and gynecology, pediatrics, family medicine).
 3. Specialized Polyclinic: a polyclinic including one or more medical specialty, and its subspecialties.
 4. Clinic: a facility where patients are received, examined, and treated.
 5. Radiology Center: a facility for medical imaging or radiotherapy.
 6. Medical Laboratory: a facility for conducting laboratory examinations.
 7. Same-Day Surgery Center: a health institution licensed to hospitalize patients for conducting medical procedures; such as minor or intermediate operations, provided that the patient is discharged on the same day, in accordance with the Implementing Regulations.
 8. Health Service Support Center: a facility that provides health or technical services required for completing therapy and rehabilitation. It includes the following:
 - a) Physiotherapy center
 - b) Optical store.
 - c) Prosthetic store.
 - d) Support centers approved as health services by the Minister of Health.
 9. Emergency Medical Service Center: a unit responsible for transporting and providing first-aid services for patients or injured persons before hospitalization, in accordance with specifications and controls set forth by the Saudi Red Crescent Society ¹
- Ministry: Ministry of Health.
- Minister: Minister of Health.

The Regulation:

- 1/1. In order to be authorized for opening an Emergency Medical Service (EMS) Center, the attached conditions and specifications shall be satisfied (attached)

¹ The name of (Saudi Red Crescent Society) was changed to be (Saudi Red Crescent Authority) under the Council of Ministers' resolution No. 371 dated 1429/12/24H, as per Council of Ministers' resolution No. (68) dated 1437/02/25H

Article (2)

1. Except for hospitals, a Private Health Institution shall be exclusively owned by Saudis.
2. The clinic's owner must be a physician specialized in the clinic's area of specialty and shall supervise the clinic on a full-time basis.
3. A full-time basis supervisor shall be available in every polyclinic, medical laboratory, radiology center, or same-day surgery center. This supervisor shall be a professional specialized in the relevant area of specialty of the polyclinic, laboratory, or center, whether he is the owner or a partner thereof or otherwise. However, pursuant to the Implementing Regulations, this condition may be skipped if no Saudi physician or specialized professional is available.
4. In all cases, each Private Health Institution shall have a full-time technical supervisor specialized in the institution's area of specialty.
5. The medical director in hospitals shall be a qualified Saudi physician, as per the Implementing Regulations.
6. The management of a Private Health Institution shall be limited to properly qualified Saudis, in accordance with the controls and conditions set out by the Implementing Regulations.

The Regulation:

- 1/2 This Law and its Implementing Regulations shall be applied to Charities and Private Institutions that wish to open Private Health Institutions.
- 2/2 Requirements to be available in the technical supervisor of Private Health Institutions:
1. Holder of a bachelor's degree or its equivalent in one of the medical specialties related to the nature of work in the Private Health Institution.
 2. Received a classification from the Saudi Commission for Health Specialties.
 3. Minimum two years of experience in the nature of the work of the Private Health Institution.
- 3/2. The technical supervisor's duties shall include, but not be limited to:
1. Review and update the policies and procedures of the medical protocol in the institution and apply the best medical standards therein.
 2. Communicate with local and global scientific authorities and accreditation institutions.
 3. Infection control and reporting cases according to Ministry standards.
 4. Provide the Ministry with the necessary information where required.
 5. Care for the quality of medical services.
 6. Contribute to keeping patient safety.
 7. Approval of seconding health professionals in a way that does not conflict with the performance of the health institution and patient safety.
- 4/2. The hospital's medical director shall have:
1. Bachelor of Medicine and Surgery.
 2. Received a classification from the Saudi Commission for Health Specialties.
 3. Minimum three years of experience in an administrative position in a medical institution or has a certificate in an administrative discipline.
 4. The medical director shall be considered the technical supervisor of the hospitals.
 5. The dentist may hold the position of the medical director in specialized dental hospitals.
 6. Full-time shall be considered eight hours per day if the employer adopts the daily standard, or forty-eight hours per week if the weekly standard is adopted. Actual working hours during the Muslim holy month of Ramadan shall be reduced to a maximum of six hours per day or thirty-six hours per week.
- 5/2. The director of Private Health Institutions must be a Saudi national who holds at least a bachelor's degree.
- 6/2. The private clinic license requires:
1. The clinic's owner shall be a Saudi physician who is classified by the Saudi Commission for Health Specialties as a medical practitioner in the same area of specialty of the clinic to be licensed.
 2. Holder of a valid professional registration from the Saudi Commission for Health Specialties.

3. A licensed male or female nurse shall be available in the clinic (except for women's clinics that requires to be a female nurse). Qualified technicians may be recruited according to clinic specialty.
 4. The clinic must be equipped with the necessary facilities, furniture, and equipment according to the lists specified by the Ministry (Annex 2).
- 7/2. A full-time basis Saudi supervising physician or a professional specialized in the polyclinics, medical laboratory, radiology center, or same-day surgery center shall be hired in the following cities: Riyadh, Mecca, Jeddah, Medina, Dammam, and Khobar. The Minister may add other cities if the need arises, and the rest of the cities shall be excluded from the requirement of nationality in the absence of a Saudi supervisor. The physician, the professional owner, or the partner in the health institution may be the supervisor provided that he/she shall be specialized in the institution's nature of specialty.
- 8/2 The Directorate of Health Affairs in the region or the governorate shall be notified in case of changing the institution's director, technical supervisor or medical director in its affiliated Private Health Institutions within five working days.

Article (3)

Premises of a Private Health Institution shall conform to the sanitary conditions as well as architectural specifications and proper distribution. It shall contain necessary furniture, medical and non-medical devices and equipment. The institution shall have a medical waste disposal system, an infection control system and a health information system. The required standards and conditions shall be specified in the Implementing Regulations.

The Regulation:

- 1/3. The premises of a Private Health Institution shall have the following general criteria and conditions:
 1. Fulfillment of the technical and engineering specifications issued and approved by the Ministry or Saudi Central Board for accreditation of healthcare institutions (CBAHI) or their approved Engineering Consultancy Offices.
 2. Medical devices must comply with the standards approved by the SFDA.
 3. All technical and engineering drawings related to the construction or modification of the Private Health Institution premises shall be submitted for review and approval by the Ministry or by one of the consulting engineering offices approved by the Ministry. The Ministry shall follow-up on the stages of construction and preparation of the required reports; the final technical approval to be submitted to the Ministry in the context of issuing the institution's final license.
 4. The site shall be in conformity with the conditions of the secretariats and municipalities in the region or governorate to which the health institution is affiliated.
 5. Safety and firefighting requirements shall be available in addition to training of personnel on firefighting methods.
 6. The Private Health Institution's license shall be placed in a visible place inside the institution, and a board shall be placed at the entrance of the institution which reflects its name and medical specialization according to the license and work schedules.
 7. All health professionals and medical staff working in the institution shall wear a business card visibly so that it shows the name and specialization according to the classification of the health specialties during the period of work at the institution. The Private Health Institution shall also be committed to developing an updated monthly list of all involved physicians.
 8. A suitable place shall be provided for patients' records (appropriate room if paper files are used. However, Private Health Institutions that operate the electronic file system shall be excluded), provided that patient file opening shall be free of charge.
 9. Means of communication shall be provided according to the needs of the Private Health Institution.
 10. Suitable places shall be reserved for men while a separate waiting area shall be dedicated to women with adequate furniture and cold water as well as adequate and suitable toilets.
 11. The premises must have entrances and exits for people with special needs which facilitate their movement inside the premises.
 12. Billboard signs shall be placed within the institution to clarify the patients' rights and duties, locations of

clinics, departments and other facilities of the institution. A panel numbered (937) shall be put to receive feedback and complaints from the outpatients and any other requirements of the Ministry.

2/3. The Private Health Institution shall be committed to the full application of the following:

1. The infection control and sterilization system includes the implementation of the Comprehensive Assessment Program for Infection Control Policies and Procedures from the Ministry and the Basic Components Program. The application reference shall be the National Infection Control Handbook. The obligation to report cases shall be according to the mechanism established by the Ministry (Annex 3).
2. Safe disposal system of medical wastes shall be subject to the Implementing Regulations of the GCC Health Care Waste Management System (Annex 4) issued by the ministerial resolution No. (60567/2/22) dated 1427/07/18H approved by the royal decree No. (M/53) dated 1426/09/16H and contracting with a company approved by the General Authority for Meteorology and Environmental Protection for the safe disposal of medical waste.

3/3. The Private Health Institution shall have an information system (medical records) appropriate for the nature of work in accordance with the Ministry's standards (Annex 5).

Article (4)

1. **No Private Health Institution may be opened or operated except after completing all conditions and requirements stipulated in this Law and its Implementing Regulations, upon obtaining all necessary licenses.**
2. **Health institutions shall be granted a renewable five-year license.**

The Regulation:

- 1/4. The license shall be granted for opening private hospitals, same-day surgery centers, addiction centers, telehealth centers, telemedicine and independent home medical centers with the approval of the Assistant Agency for Health Investment Development. The Ministry issues and renews all licenses to other health institutions.
- 2/4. The Private Health Institution may, subject to the approval of the Ministry, contract with a company or institution that is specialized in the operation of Private Health Institutions, provided that such company or institution is accredited by the Ministry according to the attached mechanism (Annex 6).
- 3/4. The application for a license to open a Private Health Institution shall be submitted to the competent health affairs directorate. The procedures and dates of the licensing stages shall be determined according to the following:
 1. Stage 1: Initial approval shall be issued after completion of the required documents and data according to the Annex (Annex 7).
 2. Stage 2: Upon completion of the project, the investor submits the final license application, and then the inspection committee of the investment development directorate shall inspect the premises, equipment and cadres. The inspection report shall be issued within ten working days from the date of submitting the application.
 3. Stage 3: The final license shall be granted to the institution and the cadres working therein after obtaining the certificate of professional classification from the Saudi Commission for Health Specialties.
- 4/4. The license duration for any Private Health Institution shall be only five years commencing from the date of granting the final license. The license shall be renewed for a further period after making sure of the existence of all conditions and requirements stipulated in this law and its Implementing Regulations under which the institution was licensed.

Article (5)

An applicant for license to open a Private Health Institution or renewal thereof shall pay the prescribed fee as follows:

Private Health Institution	License or Renewal Fees
Hospital with 50 beds or less	5000 Saudi Riyals
Hospital with 50 beds to 100 beds	10000 Saudi Riyals
Hospital with more than 100 beds	15000 Saudi Riyals
General polyclinic	2000 Saudi Riyals
Specialized polyclinic	2000 Saudi Riyals
Clinic	1000 Saudi Riyals
Radiology center	1000 Saudi Riyals
Medical laboratory	2000 Saudi Riyals
Same-day surgery center	2000 Saudi Riyals
Health service support center	1000 Saudi Riyals
Emergency Medical service center	1000 Saudi Riyals

Article (6)

A Private Health Institution shall be classified, upon obtaining or renewing the license, according to criteria and conditions set by a specialized committee. The Implementing Regulations shall specify this committee and determine classification procedures and manner of implementation.

The Regulation:

- 1/6. The committee shall be established under the chairmanship of the Assistant Agency for Development of Health Investment and membership of the Assistant Agency for Compliance, the General Directorate for Quality and Patient Safety, the Saudi Center for Health Facilities Accreditation and the Saudi Center for Patient Safety. The committee shall classify Private Health Institutions according to the standards established by the Committee. Provided that the committee shall take into account the Private Health Institutions' visions before the adoption of standards.
- 2/6. The Committee shall undertake the classification procedures and the mechanism for applying the approved standards.
- 3/6. The classification results shall be published by the Ministry periodically.

Article (7)

Each Private Health Institution shall determine the average rate for services rendered by it, and then to be approved by the Ministry after reviewing thereof and ascertaining of its appropriateness in accordance with the criteria it establishes. These rates may not be amended unless approved by the Ministry, and the institution shall be committed to the following:

1. The approved health services rates
2. Placing the rates in a visible place and shall be written clearly.
3. Provide the reviewer with an approximate report of the cost of treatment before starting thereof and services to be rendered thereto.
4. Provide a final detailed statement of the type of treatment and services rendered thereto and the cost of each service rendered.

The Regulation:

- 1/7. A committee shall be established under the chairmanship of the Assistant Agency for Development of Health Investment and membership of the General Directorate of Service Procurement to establish the appropriate mechanisms and criteria for accrediting the average rate of health services rendered by Private Health Institutions.
- 2/7. The institution shall publish the prices approved by the Ministry in soft or hard copy.
- 3/7. The patient's written consent for the cost of the treatment shall be obtained and included in the patient's medical record, except for emergency cases that require immediate intervention.
- 4/7. The Private Health Institution shall be obliged to provide the patient with a free of charge review within at least fourteen days for the same condition that was diagnosed in the initial examination.

Article (8)

A Private Health Institution may not hire physicians or other health practitioners or pharmacists except after obtaining a practice license from the Ministry.

The Regulation:

- 1/8. The Ministry shall grant the license to practice the profession based on the requirements set forth in the Law of Practicing Healthcare Professions and its Implementing Regulations.
- 2/8. Secondment may be allowed among Private Health Institutions according to the following regulations:
 1. Both institutions shall have valid licenses.
 2. The health practitioner holds a valid profession license.
 3. The secondment may be within or outside the Directorate of Health Affairs in which the Private Health Institution is located and where the health practitioner is licensed.
 4. The approval of the directorates of health affairs in the regions or governorates to which the two health institutions between which the secondment shall be carried out prior to the health practitioner's employment for the institution requesting the secondment shall be obtained. Provided that this does not lead to the lack of specialization in the seconding institution.
 5. The secondment duration shall not exceed one hundred and eighty days (consecutive or intermittent) during the same year, provided that the seconded health practitioner license is valid during the secondment duration.
 6. Health workers working in the health establishment may be transferred to other employer's health institutions (the sponsor). The institution shall keep records for the documentation of the movement of health practitioners among institutions.
- 3/8. Health practitioners may be licensed by the recruitment companies and Ajeer Business Services in the name of the Private Health Institution, which will work with a temporary license, after fulfilling the following:
 1. All the requirements stipulated in the Law of Practicing Healthcare Professions and Law of Private Health Institutions.
 2. Attach a copy of the Ministry of Labor's license Attach a copy of the Ministry of Labor's statement to the recruitment company that will hire the health staff.
 3. A copy of the health practitioner services hiring contract between the Private Health Institution and the recruitment company, indicating the name of the health practitioner, his passport number, residence number, classification card number and registration number in the Saudi Commission for Health Specialties, and the date of work commencement and termination at the Private Health Institution.
 4. When licensing new Private Health Institutions, the health practitioners' contract duration in Ajeer Business Services shall not be less than one year, and renewed when needed.
 5. The Private Health Institution shall abide by the provisions of Article (41) of the Law of Practicing Healthcare Professions issued by the Royal Decree No. (M/95) dated 1426/11/04H, which stipulates that: (subscription in cooperative insurance against medical professional errors is mandatory for all physicians and dentists working in public and Private Health Institutions. These institutions and facilities shall guarantee the payment

of compensation by a final judgment against their subordinates if insurance coverage is not available or insufficient, and has the right of recourse against the sentenced person in the payment made to him. This compulsory cooperative insurance may include other categories of health practitioners under a resolution of the Council of Ministers based upon a proposal of the Minister of Health.

6. Private Health Institutions as well as recruitment companies shall notify the Ministry in the event of the health practitioner's contract termination under Ajeer Business Services or recruitment companies before the specified period under which the license was obtained by the Ministry.
- 4/8. Private hospitals and polyclinics that are ready for the specialization and possibilities of the visiting physician may request the recruitment of visiting physicians and extract visas for them through the health affairs directorates to which the Private Health Institutions are affiliated in accordance with the rules set forth in Article 3 (b) of the Law of Practicing Healthcare Professions.
- 5/8. The Saudi consulting physicians' work in the different specialties in the private health sector shall be determined according to the following rules:
 1. The Saudi Consulting Physician who has a classification from the Saudi Commission for Health Specialties may work at a maximum of two Private Health Institutions, except for the consultant physician licensed at the Same-Day Surgery Center.
 2. The Saudi Consulting Physician is required to work in two Private Health Institutions to obtain two licenses to practice the profession in both institutions.
 3. The health affairs in the region or the governorate shall be provided by with the consulting physician's work schedule at each Private Health Institution, and inform the health affairs upon his cessation of employment in one of the licensed institutions.
- 6/8. The obtaining of the following documents by the Saudi consulting physicians who are faculty members at the universities shall be considered a license to practice the profession in the private sector:
 1. Registration and classification from the Saudi Commission for Health Specialties.
 2. Approval of the Minister of Education to work in the Private Health Institution.

Article (9)

The number of beds may not be less than thirty beds in a general hospital; twenty beds in a bi-specialized hospital; and ten beds in a mono-specialized hospital.

The Regulation:

- 1/9. The license shall be granted to the hospital according to the procedures manual for granting private hospital licenses (Annex7).
- 2/9. In addition to the provisions of Article 3/1, the hospital premises must comply with the technical and engineering specifications as per the requirement of Ministry or Saudi Central Board for accreditation of healthcare institutions (CBAHI) (Annex 8) with the need to consider the following:
 1. Arrange sections in a practical way that facilitates the movement of employees and outpatients; the corridors shall be wide, with the need for guidance boards for the various sections and services.
 2. Provide a standby electricity source that works automatically after the general power failure with sufficient power to operate the main sections of the hospital, especially operating rooms, delivery, blood bank, ambulance, intensive care and the main corridors of the hospital, with testing this source constantly to ascertain its validity.
 3. Provide all sanitary and technical conditions in sanitary installations to prevent contamination or chaos.
 4. Provide the appropriate number of elevators with sufficient capacity to transport the patients' beds if the hospital consists of two or more floors in a manner commensurate with the capacity of the hospital.

Article (10)

A hospital shall have an adequate number of resident physicians, specialists, consultants, pharmacists, technicians, nurses, ancillary health staff and other necessary services on the basis of hospital capacity and level of classification, in accordance with standards and controls set forth by the Implementing Regulations.

The Regulation:

1/10. Hospital Staff

1. The hospital must have a manager with adequate experience and training to manage the hospital and be responsible for supervising the hospital and developing appropriate plans for its evolution, ensuring its good performance.
2. The hospital shall appoint a medical director who fulfills the conditions stipulated in Article (4/2) of these Regulations.
3. The hospital shall appoint a qualified nursing head with at least five years' experience in nursing supervision.
4. The hospital shall appoint a number of consulting physicians, registrars and residents physician according to specialization, so that the consultant would not supervise more than 30 beds while the registrar would not supervise more than twenty beds, providing at least one resident physician for every twenty-five beds in each period.
5. The minimum number of physicians, specialists, and technicians shall be provided to ensure continuous coverage of auxiliary medical services such as laboratory and radiology.
6. Adequate numbers of nurses shall be provided covering inpatients, outpatient clinics, ambulances, intensive care, and operations.

Article (11)

A Hospital shall be equipped with the following:

1. **Necessary medical devices and equipment; a laboratory and radiology unit based on specialty; isolation rooms; intensive care beds; and all required ambulatory services as per the Implementing Regulations.**
2. **A dispensary satisfying terms and specifications in accordance with the Pharmacy Practice Law and its Implementing Regulations.**

The Regulation:

1/11. Hospital Departments and Services:

The hospital shall be equipped according to the checklists prepared by the Ministry; provided that the general hospital shall have the following sections as a minimum:

1. Medical Services:

- A. Outpatients:
- B. Laboratory
- C. Emergency section. An ambulance registrar physician and at least two nursing staffs are required throughout the day, a fully equipped isolation room and an ambulance are equipped to transport emergency cases.
- D. Radiology. Contains general X-ray machines, ultrasound, and CT machines for hospitals with a clinical capacity of 100 beds or more.
- E. The surgical suite of the hospital which has surgery departments shall include the following:
 1. Maternity Ward
 - a) Hospitals that have maternity wards shall include at least two fully equipped rooms for natural childbirth, an equipped operation room, a special room for Neonatal, a special room for prematurely born infants with at least %20 of maternity ward beds, and all mothers shall be allowed to have escort during childbirth while providing continuous moral and physical support.
 - b) Compliance with the Ministry's criteria related to cesarean operations, episiotomy, and vaginal

2 The Law was changed to (Law of Pharmaceutical Preparations and Installations) issued by Royal Decree No. M/31 dated 1425/06/01H.

delivery rate after cesarean operations as per (Annex 9).

- c) Hospitals that have obstetrics and gynecology departments or a pediatric ward shall provide a breastfeeding support clinic with a female physician or health educator who is trained in breastfeeding counseling to support a pregnant or breast-feeding mother. The hospital shall be committed to the Law of Trading in Breastfeeding Substitutes issued by Royal Decree No. (M/49) dated 1425/09/21H for hospitals and centers where the services of women, obstetrics, and gynecology are rendered.

2. Convalescence Wards.
3. Isolation ward to receive non-critical infectious disease cases and follow the necessary preventive measures.
4. Provide negative pressure isolation rooms for air-borne diseases in accordance with Ministry specifications and equipped with a separate toilet at a rate of one room per 25 beds, and at least one room in the inpatient department.

F. Intensive Care Department:

1. Hospitals with operation rooms shall provide a number of intensive care beds suitable for the hospital size and area of specialty with the percentage of one intensive care bed per operation room, and not less than one bed per 10 beds, or %10 of the hospital's clinical capacity.
2. Provide at least one negative pressure isolation room for each 6 compliant intensive care beds.
3. An intensive care consultant shall be responsible for supervising the department and shall be directly related to the hospital's medical director.
4. The intensive care unit shall be equipped with the necessary equipment and furniture (artificial respirators, bronchoscope, a rapid intervention vehicle equipped with a defibrillator, emergency drugs and equipment, blood oxygen measuring device, heartbeat and biomarkers, blood transfusion devices and pumps, and blood gases measure and analysis).

G. Private hospitals' blood bank:

1. Blood bank shall be equipped with medical supplies, latest equipment, and reliable examination devices recognized by competent authorities in order to enable the health institutions to collect, separate, examine and store blood and its derivatives in a safe and secure manner in accordance with the national standards of Saudi Central Board for accreditation of healthcare institutions (CBAHI) and SFDA on Good Manufacturing Practices (GMP) for blood banks.
2. When applying for a license to open a blood bank, the number of hospital beds shall not be less than 100 beds.
3. The blood bank area must not be less than 120 m² to include the following:
 - a) Donor reception room and medical examination with privacy.
 - b) Components preparation and separation department.
 - c) Conservation section of components that have not been checked for diseases (refrigerator, deep chillers, Platelet Incubation).
 - d) Conservation section of checked components for diseases (refrigerator, deep chillers, Platelet Incubation).
 - e) Laboratory tests section, including tests of infectious diseases transmitted by blood.
 - f) Various tests section for blood samples of patients and donors (compatibility, blood type, antibodies).
 - g) Repository to store supplies and reagents
 - h) Section for receiving requests of blood transfusion, its components and releasing thereof.
 - i) A room for the registration of donors' information and test results electronically.
 - j) Provide security and safety measures in accordance with safety and health guide in medical laboratory issued by the World Health Organization.
4. The existing blood banks in private hospitals shall comply with all the construction conditions and specifications included in these Regulations.
5. Blood banks in private hospitals shall have at least one senior registrar physician (blood bank/ clinical pathology/ blood diseases) with at least three years of experience in the field of blood banks with the availability of three staff (laboratory specialist- (2) laboratory technicians- (2) nursing technicians/ or blood

draw health assistant.

6. Private hospitals that do not have blood bank shall secure blood units and their components from other health sectors free of charge. A separate section within the laboratory must be equipped to carry out blood cell tests, compatibility tests, storage of blood units and components, and a blood bank refrigerator, a deep cooling refrigerator for plasma, and platelet incubation). The hospital shall be obliged to perform the above tests and to supervise the blood transfusion according to the pricing of services approved by the health affairs.
7. General conditions for blood banks in private hospitals:
 - a) Commitment to Royal Decree No. (255) dated 1422/12/08H, includes limiting the donation of blood to voluntary donations only.
 - b) The necessity of adhering to the code of practice in blood banks and circulars organized for blood transfusion service issued by the competent authorities in the Ministry.
 - c) Commitment of all blood banks in private hospitals that draw blood from blood donors with the financial value of blood unit price or its components which have been determined by the specialists in the General Directorate of Laboratories and Blood Banks in the amount of five hundred Saudi Riyals only, currently or any future regulations in this regard from the General Directorate of Laboratories and Blood Banks in exchange for (empty blood bag, serological tests, ELISA test, DNA test, determine blood type, compatibility test, blood transfusion device, medical supervision of blood transfusion).
 - d) Blood banks are prohibited from engaging in any additional activities such as collecting frozen fresh plasma for the purposes of plasma derivative manufacturing or cord blood bank.
 - e) It shall be confirmed that blood is free of all infectious diseases recognized in international and local standards using reliable testing equipment and techniques with sensitivity and accuracy of results and recognized in accordance with the national standards of Saudi Central Board for accreditation of healthcare institutions (CBAHI) and SFDA on Good Manufacturing Practices (GMP) for blood banks (Annex 10).

2. Administrative Services

- A. A management section in which rooms for the hospital director, assistants, and administrative and accounting personnel.
- B. A reception at the entrance to the hospital is supervised by a staff member who speaks Arabic fluently and is able to guide visitors, and provide them with the necessary information.
- C. An appointment office to set visit schedule for the patient.
- D. A Medical record department, taking into account what is stated in the Regulation (3/3).
- E. A special file for each patient that includes all his reviews of the different sections of the hospital.
- F. Provide the appropriate place and qualified personnel to organize and save medical files.
- G. A file shall be opened for the patient for free and it shall include the following:
 1. The patient identification data
 2. The health record number
 3. A system to alert employees to patients of the same name.
 4. The time and date of the patient's visit
 5. A full patient record including: (biomarkers data, basic complaint, current disease, social and psychological status, drugs allergies, family medical history, current complaint, and medical history):
 6. A physical examination as per the applicable system.
 7. The diagnosis of case acceptance
 8. All reports of diseases, laboratories and radiology tests.
 9. The physicians' diagnosis and instructions.
 10. The pain condition assessment
 11. Documentation of all services rendered include care and medical and surgical treatment, signed and sealed by the attending physician.
 12. A final discharge summary.
 13. A discharge card: it shall be given to the patient free of charge.

14. The results of the autopsy, the death certificate, and the death files shall be kept in the hospital throughout the hospital period of work.
15. Child vaccination records.

- H. Registration of births and deaths electronically within the regulations issued by the Ministry (Annex 11).
- I. The hospital shall keep the patients' files for ten years including the last visit of the patient and when destroyed after this period, the hospital keeps a summary of the medical condition for reference when necessary.
- J. Provide prescription files or printable electronic prescriptions when requested by the patient or inspection committees.

3. Support Services inside the Hospital

- A. Workers in the kitchen, laundry, hygiene, and sterilization must have health certificates proving that they are free from infectious diseases.
- B. Nutrition:
 1. All sanitary and technical conditions shall be available at the kitchen for preparing, preserving, and serving the food in accordance with Hazard Analysis and Critical Control Points (HACCP) standards.
 2. The hospital management shall be committed to providing a nutrition system in line with all regulations issued by the Ministry in the field of nutrition
- C. Laundry: The hospital must have a special section equipped with all the machines and equipment that provide cleaning, washing, ironing clothes and blankets or outsourcing these services in accordance with the technical and health standards through contracting with a specialized company.
- D. Hygiene:
 1. A good level of hygiene shall be provided in each section of the hospital and by trained workers in hygiene.
 2. Independent hygiene services shall be provided for operations, obstetrics, and intensive care departments.
 3. The hospital may hire a company specialized in the field of hygiene.
- E. Sterilization:
 1. The hospital shall have a special department equipped with all machines and equipment that secure the sterilization process in a safe manner according to the technical and health principles and a specialized company may be outsourced.
 2. The department's design shall be carried out in accordance with the specifications of the Ministry as well as ensure quality control tests for the sterilization process.
 3. The hospital must be provided with a morgue refrigerator according to the accepted medical methods and at least four corpses per 100 beds.
 4. A licensed security guard company shall be hired around the clock or to provide guards with sufficient numbers sponsored by the hospital.
 5. In-House pharmacy shall be managed by a licensed pharmacist to practice the profession taking into account what is stated in Law of Pharmaceutical Preparations and Installations issued by the Royal Decree No. (M/31) dated 1425/06/01H and its Implementing Regulations. A Saudi pharmacist or a Saudi pharmacy technician shall be appointed to assume the responsibility for the custody of narcotic drugs and psychotropic substances, and the nursing head or his deputy in (internal section) at the hospital shall be responsible for the custody of narcotic substances and psychotropic substances, provided that a safe and tightly controlled place is reserved for the conservation of narcotic substances and psychotropic substances in accordance with the Narcotics and Psychotropic Substances Regulations issued by Royal Decree No. (M/39) dated 1426/07/08H.

2/11. Extended medical care and convalescence hospitals may be opened in accordance with the attached conditions and Regulations (Annex 12).

3/11. Specialized hospitals may be opened to treat and rehabilitate drug addicts or to obtain a permit to add a department for the treatment and rehabilitation of addiction in existing hospitals according to the attached regulations (Annex 13).

Article (12)

A Private Health Institution shall notify the competent health authority of any infectious pathological cases immediately upon diagnosis. Quarantine cases of infectious diseases shall be directly referred to Ministry hospitals and the competent health authority shall be immediately notified. The Implementing Regulations shall specify the requirements thereof.

The Regulation:

1/12. The Ministry or the health affairs in the region or governorate shall be notified by each Private Health Institution regarding any communicable diseases in accordance with the attached mechanism (Annex 14) while complying with all the preventive instructions and procedures approved by the Ministry. The Private Health Institution shall also be obliged to notify the Ministry of the required statistical data.

Article (13)

Clinics and polyclinics shall have an adequate quantity of medications and first aid tools not intended to be sold as defined by the Implementing Regulations.

The Regulation:

1/13. The necessary medications and first aid tools shall be available in the general or specialized polyclinics according to what is stipulated in lists (Annex 15).

Article (14)

Licensing for either the general or the specialized polyclinic requires employing at least one consultant in each of the licensed major specialties and assigning at least one nurse to each clinic. As an exception, said health institutions may reduce the number of consultants in remote areas determined by the Ministry to one consultant, or may have specialists only.

The Regulation:

1/14. General requirements for polyclinics:

1. Licensing for polyclinics requires employing at least one consultant or equivalent in the scientific degree of doctoral level and shall be at least a senior registrant physician.
2. The polyclinic supervisor shall be a Saudi physician who is qualified in the polyclinic area of specialty and has a valid professional license from the Saudi Commission for Health Specialties in the following cities: Riyadh, Mecca, Medina, Jeddah, Dammam, and Al-Khobar.
3. A registrant physician may be sufficient in polyclinics in all regions and governorates, except for the cities mentioned in paragraph 2 of Regulation No. (1/14) above.
4. The clinics shall be equipped with the needed facilities, furniture and equipment in accordance with lists attached to these Regulations (Annex 2).
5. The general or the specialized polyclinics may not conduct deliveries unless in emergency cases only, provided a detailed case-by-case report shall be submitted to the health affairs in the region or the governorate with proof of eligibility and the use of a birth notification system as attached (Annex 11).
6. The general or the specialized polyclinics that have obstetrics and gynecology departments or a pediatric ward shall be committed to the Mother Milk Circulation System issued by Royal Decree No. (M/49) dated 1425/09/21H for hospitals and centers where the services of women, obstetrics and gynecology are rendered.

2/14. The polyclinics shall meet the following requirements:

1. The licensed physician under paragraph (1) of the Regulation No. (1/14) shall be specialized in one of the basic specialties described in paragraph (2) of Article (1) and at least one registrant physician for each other specialty.
2. Three clinics at least shall be available for examination and each clinic shall have a licensed male or female

nurse, and qualified technicians may be utilized as per the clinic's area of specialty.

3. Provide emergency section and secure state-of-the-art ambulance provided its model not less than five years prior to the date of applying for the final license or ten years of renewal and equipped according to the attached list (Annex 16), or signing an agreement with a public or private ambulance service center.

3/14. A senior registrant physician shall be employed in the specialized polyclinics in each specialty, provided that three clinics at least shall be provided in each specialty and a registrant physician at least is sufficient for each clinic.

4/14. The physicians employed in the polyclinics or clinics are prohibited to perform operations in hospitals unless after the health affairs directorate being notified thereof according to the following controls:

1. Operations shall be performed by the polyclinics or clinics' physicians within the limits of the powers and privileges entitled to hospital physicians.
2. Both parties share the liability in case of violating the health regulations related to the Private Health Institutions and their employees.
3. The hospital provides the required specialization.
4. The physicians employed in the polyclinics or clinics are prohibited to receive or examine patients within the hospital.

Article (15)

Services of the laboratory, radiology center, same-day surgery center, and health service support center, irrespective of type, shall be rendered by licensed specialists. The Implementing Regulations shall specify the conditions and work procedures for providing such services as well as the required qualifications of workers.

The Regulation:

1/15. Medical laboratories conditions and controls

1. The laboratory area must be adequate and contain the necessary facilities so that the quality of work and the safety of employees and visitors will not be affected in accordance with national and international standards. The laboratory shall be equipped with precision equipment and reliable examination apparatus with accurate outcomes and recognized by competent authorities to enable the health institution to provide laboratory services in an appropriate and safe manner according to national standards of the Saudi Central Board for accreditation of healthcare institutions (CBAHI).
2. Medical laboratories are classified into general laboratories and specialized laboratories. The laboratory may be independent or within a Private Health Institution, as follows:
 - A. General laboratories, specialized in routine non-specialist medical analyzes including full blood image, blood group, biochemistry, image elements, serological interactions, microbiology.
 - B. Specialized laboratories, specialized in performing specialized medical analyzes include (immunology, histology, tissue compatibility, cellular genetics).
3. Laboratory Staff
 - A. The hospitals' laboratory official-in charge shall be a laboratory consultant or consultant not a physician in the laboratory area of specialty as a minimum and licensed to practice the profession, in addition to laboratory specialists and technicians in each specialization of laboratory various specialties.
 - B. The polyclinics' laboratory official-in charge shall be a registrant physician or laboratories senior specialist as a minimum and licensed to practice the profession in addition to laboratory specialist and (2) laboratory technicians.
 - C. Independent laboratories shall provide a consultant not a physician in the laboratory area of specialty or laboratory senior registrant physician in major cities (Riyadh, Mecca, Medina, Jeddah, Dammam, and Al-Khobar), and laboratory registrant physician may be enough in other cities.
4. Laboratory facilities and equipment
 - A. Reception office to receive outpatients and an independent room equipped for sample collection.
 - B. Sufficient area for various tests and an independent room in case of germ tests.

C. The general laboratory and the specialized laboratory shall be equipped as per (Annex 17).

5. Laboratory Tests

Each laboratory shall submit, at the time of the license or renewal, a statement of all types of diagnostic devices used, and a sheet of lab tests performed and the average rates, and that the tests allowed for general and specialized laboratories as follows:

- A. The tests outlined in the attached (Annex 17) shall be carried out in the general laboratory.
- B. Specialized laboratory tests, as well as routine laboratory analyzes, shall be carried out as per the laboratory area of specialty in case that the necessary equipment indicated in the Annex is available (Annex 17).

6. Analysis data

Results of tests and examinations shall be recorded on printed forms for each of the laboratory departments and contain the following data:

- A. The laboratory name, address and license number – the name of the relevant department - patient's name and address - ID or residence permit number - date - referral entity - the serial number in the record - sample type and examination required - examination result - examiner name and signature - laboratory director signature and seal.
- B. The laboratory reports shall include printed limits and standard natural rates for all types of tests according to the methods used in the laboratory. The reviewer shall be given the original report and a hard or electronic copy thereof shall be kept in the laboratory.

7. If an independent private laboratory or other Private Health Institution wishes to send or receive laboratory samples from other Private Health Institutions, the procedures for such use shall be followed as per the attached (Annex 17).

2/15. Conditions and controls of radiology departments:

Radiology departments in hospitals shall provide a sufficient number of physicians as follows at a minimum:

1. Hospital with a clinical capacity of less than 100 beds shall have at least one radiologist.
2. Hospital with a clinical capacity ranges between (200-100 beds) shall have at least one radiologist and senior registrant radiologist.
3. Hospital with a clinical capacity of more than (200 beds) shall have at least two radiologists and senior registrant radiologist.
4. Opening of a radiotherapy department in the hospital requires providing specialized consultants in this area of treatment.
5. The independent radiology centers or the radiology departments in polyclinics shall comply with the general standards, conditions and requirements set out in Articles 3/1 and 3/3 of these Regulations. The department shall be administered by radiologists as follows:
 - a) A senior registrant radiologist in independent radiology centers and a registrant radiologist in polyclinics are required if the existing machines contain only X-ray machines and ultrasound machines.
 - b) A consultant radiologist in the independent radiology centers, and a registrant radiologist in polyclinics are required if the existing machines contain X-ray, ultrasound, CT or magnetic resonance machines.
 - c) An interventional consultant radiologist is required to perform interventional radiology.
 - d) The interventional vascular radiology may be carried out at radiology centers in polyclinics according to the attached conditions (Annex 18)
 - e) The radiologist may supervise more than one polyclinic belonging to the same owner of the health institution.
6. The Teleradiology Center (the institution authorized to prepare radiographic reports), the following is required:
 - a) For licensing Teleradiology Center, an application shall be submitted to health affairs directorates in the regions and governorates and shall be referred to the Assistant Agency for Health Investment Development in the Ministry.

- b) The Teleradiology Center shall be evaluated every two years, and the radiographs shall be maintained for at least two years.
- c) Minimum equipment shall be provided as attached (Annex 19).
7. Special provisions for radiology departments and centers
 - a) Preparing CT and MRI reports shall be performed by specialist physicians in diagnostic radiology not less than a senior registrant physician.
 - b) Preparing specialized mammography reports shall be to be performed by a senior registrant radiologist as a minimum and has specialized rehabilitation in mammography.
 - c) The department or the center shall have a Policies and Procedures Manual.
 - d) The approval of the Ministry shall be obtained if the Independent Radiology Center or the Radiography Department within another health institution wishes to receive radiographs from other Private Health Institutions in accordance with the procedures regulating thereof.
8. General provisions of radiology departments in Private Health Institutions:
 - a) The quality program of radiation devices in Private Health Institutions shall be applied periodically and their reports shall be sent to radiation protection departments in their respective regions or governorates.
 - b) Provide an official in charge of radiation protection in the health institution and directly reported to the institution director.
 - c) Licensing or renewal of Private Health Institutions licenses requires securing radiation dosimetric cards for radiation workers, the application of the quality assurance program on radiation machines, and sending the results to radiation protection departments in their respective regions or governorates.

3/15. Conditions and controls of Same-Day Surgery Center

1. The same-day surgery center may be opened either independently or within a polyclinic on the necessary controls for same-day surgery.
 - a) Same-day surgery permit shall be granted to a consultant in the area of specialty who meets the conditions provided that the application is submitted along with the lists of operations that will be performed by him.
 - b) The Center shall provide an adequate number of physicians, specialists and technicians (Annex 2).
2. Conditions for same-day surgery license
 - a) The physician shall obtain approval of the Assistant Agency for Health Investment Development After meeting all the conditions and controls related to same-day surgery.
 - b) Compliance of same-day surgery center with the conditions, specifications, and equipment (Annex 20).
 - c) A valid agreement with a private or government hospital to accept emergency cases that require referral to hospitals at any time.
 - d) Acknowledgment that the patient should not be allowed to stay at the center for any reason whatsoever and emergency cases shall be referred to the hospital.
 - e) Acknowledgment of the physician to be licensed that he bears full responsibility for any negligence occurring to the patient.
 - f) Appointment of an official responsible for the custody of narcotic substances and psychotropic substances for use within the Center in accordance with the Law of combating narcotic drugs and psychotropic substances and its Implementing Regulations and annexed Procedures manual (Annex 21)
3. General Provisions:
 - a) The surgery fees shall be determined and the patient shall be notified thereof in a written form signed by the patient before it is being performed and recorded in his medical record.
 - b) A license granted for a physician licensed to perform same-day surgery shall be considered a personal license and any other unlicensed physician shall be prohibited from practicing this specialty.
 - c) A license granted for a physician licensed to perform same-day surgery shall be valid for one year and shall provide a comprehensive report to the Assistant Agency for Health Investment Development regarding the surgeries undertaken. Then this license shall be renewed regularly as stipulated in

Article (2/3L) of the Implementing Regulations of the Law of Practicing Healthcare Professions issued by Royal Decree No. (M/59) dated 1426/11/04H.

4/15. Ancillary Health Services

1. Ancillary health services centers include:
 - a) Immediate Medical Care Centers (Annex 22).
 - b) Mobile Medical Clinics (Annex 23).
 - c) Tele-Health and Telemedicine Centers (Annex 24).
 - d) Home Medical Care Centers (Annex 25).
 - e) Palliative Care Centers (Annex 26).
 - f) Addicts Rehabilitation Specialized Centers (Annex 27).
 - g) Medical Rehabilitation Center (Annex 28).
 - h) Physiotherapy Centers (Annex 29).
 - i) Occupational Therapy Centers (Annex 30).
 - j) Prosthetics and Orthotics Centers (Annex 31).
 - k) Speech, communication & Swallowing Rehabilitation Center (Annex 32).
 - l) Hearing Diseases Treatment Centers (Annex 33).
 - m) Psychotherapy and Rehabilitation Centers (Annex 34).
 - n) Optical Store (Annex 35).
 - o) Dental Protheses Laboratories (Annex 36).
 - p) Foot and Ankle Care Centers (Annex 37).
 - q) Nutrition Centers (Annex 38).
 - r) Medical Larvae Production Centers (Annex 39).
 - s) Kidney Dialysis Centers (Annex 40).
 - t) Any other services and centers issued by a decision of the Minister.

2. Centers Conditions and Specifications

The ancillary health centers shall comply with the general standards and conditions required in the Private Health Institutions mentioned in Articles (3/3 -1/3) of this regulation. The conditions and specifications, as a minimum, of each center shall also be met (in accordance with the regulations and guidelines set by the Ministry under these Regulation); cadres licensed to practice the profession shall be employed under specialized supervision in the center area of specialty.

5/15. Additional specialties and activities

1. The approval to add any health specialty in the health institution requires the staff with an additional registration of this specialty from the Saudi Commission for Health Specialties and an additional license from the Ministry of Health, and these specialties include:
 - A. Laser treatment.
 - B. Palliative treatment.
 - C. Endoscopic Surgery.
 - D. Gastrointestinal Endoscopy for non-Gastroenterologist.
 - E. Hair transplant.
 - F. Dental implant.
 - G. Ultrasound diagnosis (for non-radiologists).
 - H. Ultrasound diagnosis for obstetricians and gynecologists (for gynaecology and obstetrics).
 - I. Heart Electrophysiological diagnosis and analysis.
 - J. Any other specialty recommended by the Saudi Commission for Health Specialties to be added and approved by the Minister of Health.
2. Approval of health affairs in the region or governorate shall add any of the following activities in accordance with the technical requirements and conditions attached to the Regulations:

- A. Examination of expatriate workers and food workers in hospitals and polyclinics (Annex 41).
- B. Infertility and IVF according to the provisions of the Law of Fertilization and Embryology Unit and infertility treatment issued by Royal Decree No. (M/76) dated 1426/11/21 H and its Implementing Regulations (Annex 42).
- C. Circumcision in hospitals and polyclinics (Annex 43).
- D. Obesity Surgery Unit in hospitals (Annex 44).
- E. Gastrointestinal Endoscopy Unit in polyclinics (Annex 45).
- F. Chemotherapy of tumors in polyclinics (Annex 46).
- G. Office surgeries in private clinics and polyclinics (Annex 47).
- H. Any additional activities approved by the Minister.

Article (16)

A Private Health Institution shall providing first-aid treatment to all incoming serious emergency cases without any financial claims prior to providing treatment, in accordance with the Implementing Regulations.

The Regulation:

1/16. Emergency sections in the Private Health Institutions emergency sections shall provide first-aid medications listed in the attached list (Annex 15).

2/16. First-aid treatment

The Private Health Institution shall be committed to provide first-aid treatment to all incoming serious emergency cases without any financial claims prior to providing treatment, taking into consideration the following:

1. First-aid case: means the case resulting from an injury or illness that may threaten the life of the patient or one of its internal or external limbs or organs
2. First-aid: means the urgent medical procedures required by the patient's case and leads to the stability of his condition in a way that allows him to be transferred.
3. The necessary tests in emergency cases: means the tests that are indispensable for diagnosing the patient's condition or determining the treatment method.

3/16. Emergency cases treatment rules (Annex 48).

Article (17)

Committees for inspection of Private Health Institutions shall be formed in each directorate of health affairs to ensure implementation of the provisions of this Law and its Implementing Regulations as well as decisions issued by the Ministry under this Law, and to monitor quality level. The Implementing Regulations shall determine the manner of formation of said committees as well as their work procedures.

The Regulation:

1/17. A committee or more shall be formed by a decision of the director of health affairs in each health directorate with at least two members to inspect the Private Health Institutions. Each committee shall be committed to the uniform, tags, and minutes on the Ministry approved official forms. Experienced and qualified members with university qualifications commensurate with the nature of the task are required to be selected, and the members may be selected from outside the Ministry.

2/17. The inspection committee of the health affairs directorate shall perform the following tasks:

1. Ensure the commitment of the Private Health Institution to the provisions of the Law of Private Health Institutions and its Implementing Regulations and decisions and instructions issued by the Ministry.
2. Monitor quality the level in each Private Health Institution.

3/17. Members of the Inspection Committee shall have the following powers:

1. Visit Private Health Institutions located within the health affairs directorate affiliated thereof.
2. Review the records, devices, and equipment; and inspect the institution's facilities, departments, and the regulatory of the cadres working therein.

3. Ensure that the Private Health Institution complies with all general and specific conditions, technical and administrative specifications, quality regulations and patient safety, and infection control.
4. The Committee shall prepare minutes in which the inspection comments shall be recorded and the documents obtained shall be attached therewith. The members of the committee shall be committed to prove the visit in the record prepared for this purpose in the health institution prior to referring the same to the Private Health Institutions violations committee after completing the approved minutes.
5. Each inspection committee shall prepare a report on its activities and each health affairs directorate shall submit a monthly report about the committees' activities to the Assistant Agency for Compliance.

4/17. Self-assessment:

1. Private Health Institutions shall be subject to the self-assessment program, through which the Private Health Institution assesses its compliance with the Ministry of Health applicable laws and regulations.
2. The outcomes of the self-assessment after the approval of the supervisor of the Private Health Institution and the inspection committee shall be considered the inspection minutes mentioned in Paragraph (4) of the Regulation (3/17) above.
3. If the Private Health Institutions voluntarily notified of any irregularities, they have through the self-assessment program, a correction period shall be given to them as stipulated in the self-assessment program.
4. In case the Private Health Institution does not comply with the corrective period and without obtaining the Ministry's approval to extend the period for justified reasons, the irregularities shall be referred to the competent committee to take formal actions.

Article (18)

The license shall be revoked upon transfer of ownership of a Private Health Institution to another owner, change of the institution's activity or location without the Ministry's approval.

The Regulation:

1/18. The owner of the Private Health Institution shall obtain the Ministry's approval to transfer the institution ownership to another owner or change the institution's activity or location. If the owner does not obtain the approval, the license shall be considered null and void without the need for any action by the Ministry. The Ministry is entitled to take immediate action to close the concerned institution and to impose sanctions stipulated by this Law.

Article (19)

The license shall terminate in the following cases:

1. **Expiry of license and failure of the licensee to request renewal; however, an application may be submitted to obtain a new license upon satisfying all statutory conditions.**
2. **Lapse of six months from the death of the owner of a Private Health Institution. The heirs may retain the license for a period to be specified by the Ministry on a case by case basis, provided that the heirs request retention of the license within six months from the date of death.**

The Regulation:

1/19. License renewal:

1. The health institution shall apply for renewal of the license granted thereto at least three months before its expiry date.
2. Upon receipt of the application, the directorate shall renew the license after the completion of the legal reasons and requirements within thirty days. The health institution shall not assume any liability arising from any delay in renewing the license.
3. The license shall be renewed automatically upon receipt of a certificate of accreditation issued by the Saudi Central Board for accreditation of healthcare institutions (CBAHI) in addition to any other international accreditation recognized in the Kingdom, provided that a period not more than six months has been elapsed since it has obtained the accreditation certificate.

2/19. The health affairs directorate may retain the license and not terminate it at the request of the heirs within six months from the date of death.

Article (20)

Without prejudice to any severer penalty prescribed by another law, a person opening a Private Health Institution without a license shall be subject to the following penalties:

1. Closure of the institution and denial of the license for a period not less than six months and not exceeding two years from the date of closure.
2. A fine of not less than (10,000) ten thousand Saudi riyals and not exceeding (30,000) thirty thousand Saudi riyals, for health service support centers.
3. A fine of not less than (30,000) thirty thousand Saudi riyals and not exceeding (100,000) hundred thousand Saudi riyals, for medical laboratories, radiology centers, or Emergency Medical service centers.
4. A fine of not less than (50,000) fifty thousand Saudi riyals and not exceeding (150,000) hundred fifty thousand Saudi riyals, for clinics, polyclinics, or same-day surgery centers.
5. A fine of not less than (100,000) hundred thousand Saudi riyals and not exceeding (300,000) three hundred thousand Saudi riyals, for hospitals regardless of class.

Article (21)

Save for violations stipulated in Article (20), and without prejudice to any severer penalty prescribed by another law, a person violating any of the provisions of this Law shall be subject to one or more of the following penalties:

1. A fine of not less than (10,000) ten thousand Saudi riyals and not exceeding (100,000) hundred thousand Saudi riyals.
2. Closure of the Private Health Institution for a period not exceeding sixty days. The institution shall take all necessary arrangements to transfer inpatients to other institutions prior to closure.
3. Withdrawal of license to the effect that the licensee may not apply for a new license except after the lapse of at least two years from the date of withdrawal.

Article (22)

The legal medical committee provided for in the Law of Practicing Human Medicine and Dentistry³ shall have the power to consider the liability of Private Health Institutions for medical errors for which claims of private or public rights are filed.

Article (23)

Pursuant to a decision by the committees provided for in Article (25), the activity subject of the violation may - as a preventive measure - be suspended if there is solid evidence and presumptions of occurrence of violations substantiated in the preliminary investigation; The penalty for which, if established, shall be the withdrawal of the license or closure of the health institution.

The Regulation:

- 1/23. If the committee concerned with examining the Law of Private Health Institutions provisions' violations finds, based on the preliminary investigation carried out in the violation location by the inspection committee, that there is solid evidence and presumptions require suspending the activity which is the subject of violation, it shall take a decision to suspend the activity and immediately notify the directorate of health affairs thereof in order to take the necessary to suspend the activity of the violating health institution.

³ This Law was cancelled by the promulgation of Law of Practicing Healthcare Professions issued by Royal Decree No. (M/59) dated 1426/11/04H.

Article (24)

If closure of a Private Health Institution results in harming the patients thereof, the Ministry shall take all necessary measures to keep patients under treatment in the manner it deems fit.

The Regulation:

1/24. Except for private hospitals, a notice for the public shall be affixed at the institution entrance indicating that the health institution is closed, but for private institutions, a committee of specialists shall be formed by the directorate to consider the hospital inpatients or the outpatients of its clinics, taking into account that the serious cases shall be treated in accordance with Article (16) of these Regulations regarding first-aid treatment.

Article (25)

- 1. Committees shall be formed at directorates of health affairs pursuant to a decision by the Minister; each committee shall include three members at least, one of whom shall be a consultant in a medical profession; the second, a legal adviser, to decide any violation of the provisions of this Law and imposes stipulated penalties. Decisions of such committees shall be enforced only upon approval by the Minister or designee.**
- 2. Aggrieved parties may appeal such decisions before the Board of Grievances within sixty days from the notification date.**
- 3. The final decision imposing the penalty shall be published at the expense of the violator in three local newspapers, one of which at least is issued in i the violator's place of residence. If no such newspaper exists in said area, it will be published in the newspaper issued in the near area.**
- 4. The Implementing Regulations shall specify the term of membership of such committees and followed procedures regarding the conduct of business and notification of decisions.**

The Regulation:

- 1/25. The Committee shall consider the violations resulting from the application of the Law of Private Health Institutions and its Implementing Regulations and impose the appropriate fine within its area of competence. The irregularity severity, type and impact on the patients' safety shall be considered.
- 2/25. The membership duration in committees of irregularities resulting from the application of the Law of Private Health Institutions shall be one-year renewable from the date of its formation decision.
- 3/25. The Committee shall carry out its duties according to the following procedures:
 1. The committee's meetings shall be held twice a week or more, if necessary at the directorate of health affairs. The committee meeting shall be valid in the presence of the chairman or his deputy, the legal member and a consultant in the medical profession related to the violation, provided that its membership does not include a member of the compliance department in the region or governorate, and that the present members shall be at least three members and the committee's decisions shall be issued by an absolute majority.
 2. In its agenda, the committee shall abide by confronting the violator as stated in the investigation minutes and hear the statement of the violator or his attorney and investigating his defenses to be recorded in written minutes.
 3. The concerned parties shall be notified in writing to appear before the committee at the time and place determined by the committee.
 4. A further date of appearance shall be determined if the violator or his attorney fails to attend the meeting after informing him that the period between the date of the report and the new date shall not be less than fifteen days. In case the violator or his attorney fails to attend the second date, the committee shall complete its consideration and adjudication of the violation.
 5. The parties shall be immediately notified by the committee's decision upon issuance in a decision-making session.
 6. When a decision becomes irrevocable by the end of the appeal period or a final decision is issued, the decision shall be submitted to the Minister or his authorized representative for approval.
 7. The committee shall have the right to consult specialists in respect of its business.

- 4/25. Upon the minister or his representative's approval of the committees' decisions, their content shall be enforced, bearing in mind that the decisions may not be enforced by force as long as the objection thereof is permissible.
- 5/25. The enforcement department of the Assistant Agency for Compliance shall ensure the implementation of these decisions after their adoption.
- 6/25. Reporting through the Communications Center (937) shall be considered a written acknowledgment by the reporter of the complaint.

Article (26)

A Private Health Institution shall, prior to signing the contract with any person it seeks to recruit, explain the provisions of the Labor Law⁴, procedure guide, job description, and relevant laws applicable in the Kingdom of Saudi Arabia.

The Regulation:

1/26. Each Private Health Institution shall explain to the health practitioner the Law of Practicing Healthcare Professions and its Implementing Regulations issued by Royal Decree No. (M/59) dated 1426/04/11H.

Article (27)

A Private Health Institution shall enable health practitioners to attend continuing medical education programs in their specialty within the Kingdom or abroad, as determined by the Saudi Commission for Health Specialties.

Article (28)

All hospitals shall have a medical library therein and shall subscribe to relevant scientific periodicals within their field; other health institutions shall provide major scientific periodicals related to their specialty.

The Regulation:

1/28. The e-library may be sufficient.

Article (29)

In case of emergencies that require mobilizing all medical resources, the Minister may order the use of any Private Health Institution, or part thereof, for purposes he determines; provided that the Ministry pays fair compensation for such use.

The Regulation:

1/29. When the emergency is over, the Private Health Institution shall raise its claim of reimbursement of the costs for the directorate of health affairs in the respective region or governorate to take the necessary measures in accordance with Article 16 of this Regulation on first-aid treatment.

Article (30)

A Private Health Institution shall promptly notify the nearest competent security agency and the local directorate of health affairs of any criminal incident or death case of outpatients or inpatients. It shall as well report any criminal incident that requires the injured person to request an ambulance or be treated therein. It shall also keep a full record of all traffic accidents and injuries.

4 The Law's title was amended to "Labor Law" under the Royal Decree No. (N/51) dated 1426/08/23H.

The Regulation:

1/30. A Private Health Institution is not entitled to retain the original identity papers or to hold patients, neonatal or deceased bodies in exchange for financial dues. The health institution shall take the necessary procedures to collect its dues through the official channels.

Article (31)

A Private Health Institution may not undertake any acts of publicity that conflict with the code of professional ethics, in accordance with criteria set forth in the Implementing Regulations.

The Regulation:

1/31. A Private Health Institution may advertise in accordance with the regulations and standards specified by the Ministry (Annex 49).

Article (32)

The Minister shall issue the Implementing Regulations of this Law within ninety days from the date of publication in the Official Gazette.

Article (33)

This Law shall supersede the Law of Private Medical Institutions promulgated by Royal Decree No. (M/58) dated 1407/11/03H.

Article (34)

Licenses issued to Private Health Institutions in accordance with the laws and directives in force at the time of issuance of this Law shall remain valid. Such institutions shall adjust their status according to the provisions of this Law and its Implementing Regulations within five years from the effective date of the Implementing Regulations. This period may be extended upon approval by the Prime Minister based on a recommendation by the Minister of Health.

The Regulation:

1/34. Labors and nutrition workers testing centers, prior to the issuance of these Regulations shall adapt their conditions in accordance with Paragraph (2/A) of the Regulation (15/5) above.

2/34. The provisions of this Law and its Implementing Regulations shall apply to any disposition of ownership.

3/34. These Regulations shall supersede all previous circulars relevant to the Law of Private Health Institutions and its Implementing Regulations.

Article (35)

This Law shall be published in the Official Gazette, and shall be deemed to take effect ninety days from publication date.