

**DEMOCRATIC REPUBLIC OF TIMOR-LESTE**  
**GOVERNMENT**

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**DECREE-LAW NO. 18/2004**  
**OF 1 DECEMBER 2004**  
**ON PRIVATE HEALTH UNITS**

The health system of Timor-Leste, alongside the National Health Service institutions and in complement to it, comprises private health care institutions provided these are regulated and monitored by the State, thereby ensuring the plurality of the system and the freedom of choice of users.

It is therefore essential to define the juridical regime applicable to private health units through a realistic and sustainable licensing and operating system that corresponds to the current socio-economic conditions but that ensures the necessary quality standards to safeguard the public and individual health of citizens.

Pursuant to sections 115.1(e), 115.1(o) and 116(d) of the Constitution, the Government enacts the following that shall have the force of law:

**CHAPTER I**  
**General Provisions**

**Article 1**  
**Purpose**

The present decree-law shall regulate the licensing, operating and monitoring conditions of private health units.

**Article 2**  
**Definitions**

1. For purposes of the present decree-law, private health units shall mean any profitable or non-profitable institution, irrespective of their designation and legal form adopted, which provides medical, nursing, diagnostic or therapeutic care.
2. Private health units may assume, namely, the following modalities or types depending on the services provided:
  - (a) **Hospital**: an establishment that provides differentiated health care with the possibility of admission;



2. The licensing process shall be dealt with by the National Directorate of Health Policy and Planning and submitted to the Board of Directors for an opinion, in accordance with the provisions of the Organic Law of the Ministry of Health.

### **Article 5 Applications**

License requests shall consist of an application, to be submitted to the National Directorate of Health Policy and Planning, indicating the type of private health unit to be licensed, its respective name and location, and attaching the following information:

- (a) Personal identification and taxpayer number of the applicant as well as his or her respective residence or head office;
- (b) Business, association or foundation registration certificate;
- (c) Proposed name of the private health unit;
- (d) Types of services or specialties to be provided;
- (e) Floor plan, project and descriptive memory of the facilities;
- (f) List of technical equipment;
- (g) Name of the technical director, along with his or her respective academic and professional background and the respective registration number with the Ministry of Health;
- (h) Staffing table, indicating the required academic and professional qualifications;
- (i) Other specific information required for the specific type of private health unit under consideration.

### **Article 6 Licensing Conditions**

1. Licensing conditions shall be contingent upon:
  - (a) Checking the validity of the records;
  - (b) Checking whether the location, characteristics of the premises and equipment are in line with the type of private health unit

**Article 7**  
**License**

necessary works, the purchasing of equipments or the recruitment of the personnel needed for the smooth operation of the establishment, under penalty of license revocation and compulsory closure of the establishment.

4. The lifting of suspensions and the re-opening of establishments whose licenses have been suspended shall be object of an application and may only be authorised following a new inspection once the proofs presented have been analysed.
5. Whenever serious dangers are posed for the users or for the public health and without prejudice to the possibility of a cautionary suspension or revocation of the private health unit license, final decisions on the suspension or revocation shall always be preceded by the application of administrative penalties in accordance with Section III.

## **Article 10 Communications**

For record-keeping purposes, all decisions to grant, dismiss, renew, suspend, change or revoke licenses shall be communicated to the institution responsible for the commercial registry or to the competent entity responsible for the registration of associations and foundations.

## **Section II Establishment and Operation of Private Health Units**

### **Article 11 Establishment**

1. Private health units shall be located in salubrious and easily accessible environments with facilities for water supply, sanitation, collection and treatment of residues, power supply and telecommunications.
2. Where the public systems of water and power distribution, sanitation and residue collection systems cannot provide these services, private health units shall be equipped with the necessary alternate systems for the types of services to be provided and shall ensure their continuous operation in accordance with the existing general or specific technical rules.

### **Article 12 Constructions**

Constructions shall observe the general rules in force and shall, in any event, offer safe and sterile conditions that are compatible with the services intended to be provided by the respective facilities, and the

for approving, by statute, the specific rules that apply to the various types of private health units.

**Article 13**  
**Operation**

1. Private health units shall respect every legal, technical and deontological rule applicable to their activities and shall provide quality health care in conditions of safety, in accordance with the
2. It shall be incumbent upon the Minister of Health to approve, by statute, the manuals of good practise of the activities provided for in the present decree-law, and, where necessary, the health activities or services that the different health units may provide depending on the professional qualifications or availability of equipment.

**Article 14**  
**Assistance from Other Private Health Units**

Private health units may only resort to the health services of other private health units when the latter are registered and licensed in accordance with the applicable legislation.

**Article 15**  
**Technical Directorate and Staff**

## **Information to Patients**

Information about the staff, divided according to areas of specialty, hours of operation, price listing, and the book of complaints shall be affixed.

### **Article 17 Records**

1. It shall be mandatory to keep a registry of all patients assisted, with the respective appointment, admission and discharge dates, where relevant, including exams and treatment performed and the identification of the persons responsible for determining and performing such exams and treatments.
2. Without prejudice to the patients' right to

- (e) Temporarily close non-licensed establishments, or their autonomous parts, or establishments operating in serious violation of the applicable regulatory rules and undermining the public health or the safety of users.

## **Article 20**

### **Administrative Penalties and Fines**

The following shall constitute behaviours punishable with the following fines:

- (a) The operation of any private health unit by whoever is not a holder of the respective valid license, in violation of the provisions of Articles 4 and 9 – the minimum fine shall be of US\$1,000 and the maximum of US\$3,000;
- (b) The provision of services or the exercise of specialties not covered by the valid license, in violation of Article 7.5 – the minimum fine shall be of US\$500 and the maximum of US\$1,500;
- (c) The failure to provide the information provided for in Articles 7.3 and 7.4 and the breach of the provisions of Article 14 – the minimum fine shall be of US\$200 and the maximum of US\$500;
- (d) Private health units operating in manifestly poor conditions as regards the provision of care and treatment, in violation of the principles of good practise and of the – the minimum fine shall be of US\$1,000 and the maximum of US\$3,000;
- (e) The lack of the required material and human resources, in accordance with the present decree-law or with its regulation, or the failure to comply with general or special rules pertaining to the facilities, equipment, organisation, operation and performance provided for therein – the minimum fine shall be of US\$500 and the maximum of US\$2,000;
- (f) The failure to comply with the rules provided for in Article 46 on the protection and safety against radiations – the minimum fine shall be of US\$1,000 and the maximum of US\$2,000.

## **Article 21**

### **Offences and Penalties**

1. Offences against the provisions laid down in the present decree-law and in complementary legislation shall have the nature of administrative penalties except if they constitute crimes, in which case they shall be punishable in accordance with the penal law.
2. Negligence and attempt of negligence shall always be punishable.
3. The application of fines shall be graduated according to the gravity of the offence and the danger it poses to public health, the degree of culpability and the economic status of the offender.



4. The maximum and minimum limits of the fines shall be reduced to half where applicable to individuals.
5. The following penalties may be applied simultaneously with the fine according to the degree of culpability of the offender, the gravity of the offence and the danger it may pose to the public health:
  - (a) Loss of objects belonging to offenders;
  - (b) Closure of the facility or the closure of an autonomous part of it;
  - (c) Suspension or revocation of the license;
  - (d) Prohibition, for a maximum of two years, to exercise the activities provided for in the present decree-law.
6. Whenever a disciplinary breach committed by any health professional is detected, the Disciplinary Board of the Health Professions shall be informed of it and given the evidence collected.

## **Article 22**

### **Procedures**

1. A report shall be prepared in connection with each and every detected offence, which shall attest to the witnessed acts until proof to the contrary is produced, and such report shall serve as the basis for initiating a proceeding in relation to the offence.
2. The report of the offence shall be submitted to the Office of Health Inspection, as the competent entity, which shall investigate the case in conjunction with the National Directorate of Health Policy and Planning.
3. The offender shall be notified of the acts that constitute the offence, of the breached legislation, of the applicable penalties and of the deadline and venue for presenting his or her defence, as well as of the possibility of voluntary payment of the fine, in its minimum limit, and of the consequences of failure to pay such fine.
4. The offender may, within 20 days, present his or her defence in writing or voluntarily pay the fine, and may also present his or her defence only in relation to the gravity of the offence and the accumulated accessory penalties, once the voluntary payment has been made.
5. The competence to apply fines and accessory penalties rests with the Minister of Health, against whose final decision a contentious appeal may be lodged within 30 days.

## **Article 23**

### **Disposal of Fines**

Seventy-five percent of the proceeds arising from fines shall accrue on behalf of the state coffers and 25% of it shall accrue on behalf of a health fund to be regulated by specific decree.

**CHAPTER III**  
**Hospitals**

**Section I**  
**Facilities**

**Article 24**  
**Entrances**

Hospitals shall have different entrances for the patients, for the public and for the services and shall allow the easy transit and movement of ambulances, stretchers and wheel chairs.

**Article 25**  
**Facilities and Minimum Equipment**

The following shall be established by statute of the Minister of Health:

- (a) The minimum services that hospitals shall provide as well as their respective areas, equipment and characteristics;
- (b) The minimum areas, characteristics and equipment of the various services that are part of the hospital.

**Section II**  
**General Equipment**

**Article 26**  
**General Principle**

Hospitals shall be equipped with general equipment enabling adequate service and comfort conditions that are in line with the minimum quality and safety standards, in accordance with the ensuing articles.

**Article 27**  
**Energy Supply in Emergency Situations**

Without prejudice to the emergency lighting system, hospitals shall be equipped with an emergency generator, which shall operate automatically whenever network power failure occurs, and they shall secure:

- (a) The general lighting and sockets for theatres as well as for the labour, recovery, intensive care and emergency rooms;
- (b) Medicinal and vacuum compressed air facilities;
- (c) Telecommunications facility;
- (d) Nurse call system;

(e) Refrigeration facilities.

**Article 28**  
**Safety of Power Installations**

In theatres as well as in intensive care and neonatology units, the neutral point connection shall be of the insulated neutral type (IT), which shall ensure that the power is distributed equally between the metal parts; a busbar of equally distributed power shall connect all accessible metal parts to the various equipment, and they shall also have a monitoring system, equipped with an alarm, of the isolation of the electrical feeding network.

**Article 29**  
**Medical and Breathing Gases**

Hospitals shall be equipped with oxygen and breathing facilities.

**Article 30**  
**Disinfection and Sterilisation**

1. Hospitals shall be equipped with a steam autoclave, whose capacity shall be commensurate with the dimension of the prevacuum cycle, to ensure that the used materials and equipment they need are disinfected and sterilised and, in the event they possess theatres and delivery r

**Article 33**  
**Laundry**

Hospitals or their subcontractors shall provide the necessary clothing and shall ensure that used clothing are washed and treated and, when caring for infectious patients, they shall be equipped with the appropriate facilities and equipment, including a laundry machine with a programme for disinfection.

**Article 34**  
**Refrigeration Equipment**

Without prejudice to the refrigeration equipment essential to the fulfillment of the provision of Article 32, hospitals providing emergency, surgic-08 of the

2. Clinical directors shall be responsible for the harmonious co-ordination and operation of the assistance services as

**CHAPTER V**  
**Ambulatory Polyclinic Services**

**Article 42**  
**Facilities, Equipment and Staff**

Ambulatory polyclinic services shall be equipped with facilities, equipment and staff necessary for medical offices, nursing stations and dental offices, in accordance with the kinds of ambulatory services they provide.

**Article 43**  
**Clinical Directorate**

Where polyclinics provide medical examinations, the clinical director of the ambulatory polyclinic services shall be a medical doctor, and, where polyclinics provide pre- and post-natal assistance, the clinical director of the ambulatory polyclinic services shall be a nurse midwife.

**CHAPTER VI**  
**Medical Offices**

**Article 44**  
**Facilities and Equipment**

1. Nursing stations shall operate in areas exclusively designed for such purpose and shall be equipped with waiting, observation, treatment and sterilisation rooms.
2. Nursing stations shall be equipped with the equipment laid down in the statute of the Ministry of Health and shall, in any event, ensure that the necessary materials and equipment used are disinfected and sterilised and that the contaminated residues or residues susceptible to contamination are treated and eliminated either by incineration or by another appropriate means.

**Article 47**  
**Technical Directorate and Staff**

1. Technical directors of nursing stations shall be nurses.
2. Technical directors shall be responsible for the operation of nursing stations and for the quality of activities and exams performed therein, in accordance with the ethical and deontological rules and with the manual of good practises.
3. Nursing stations shall be staffed with duly qualified nursing or support staff, the number of which shall be commensurate with the workload.

**CHAPTER VIII**  
**Dental Offices**

**Section I**  
**Facilities and Equipment**

**Article 48**  
**Facilities**

Dental offices shall operate in areas exclusively designed for such purpose and shall be equipped with waiting, clinical and sterilisation rooms.

**Article 49**  
**Minimum Equipment**

1. Dental offices shall be equipped with the minimum number of regular and emergency equipment and shall possess the characteristics laid down in the statute of the Ministry of Health so as to secure the technical quality of the treatments performed therein and they shall, in any event, be equipped with:
  - (a) Disinfection and sterilisation equipment;
  - (b) A system to treat and control water quality;
  - (c) An own or subcontracted system to ensure the destruction, either by incineration or by another appropriate means, of contaminated residues or residues susceptible to contamination;

- (d) A system to treat contaminated residual waters or waters susceptible to contamination.
2. The installation and use of x-ray equipment shall observe the technical rules in force and with the rules laid down in Article 59.

**Section II  
Organisation and Operation**

**Article 50  
Clinical Directorate**

1. Clinical directors of dental offices shall possess qualifications that are compatible with the specialties performed therein and they shall be dentists or dental nurses.
2. Clinical directors shall be responsible for the operation of dental offices and for the quality of the activities and exams performed therein, in accordance with the ethical and deontological rules and with the manual of good practise.

**Article 51                      CHAPTER  
Staff**

Dental offices shall be staffed with duly qualified technical staff.

**CHAPTER IX  
Analysis Laboratory**

**Section I**



- (a) Disinfection and sterilisation equipment;
- (b) Refrigeration equipment;
- (c) A system to treat and control water quality;
- (d) An own or subcontracted system to ensure the destruction, either by incineration or by another appropriate means, of contaminated residues or residues susceptible to contamination, and this shall be accomplished in such a way so as not to endanger the public health and the environment;
- (e) A system to treat contaminated residual waters or waters susceptible to contamination.

## **Section II Organisation and Operation**

### **Article 54 Technical Directorate**

1. Technical directors of laboratories shall possess qualifications that are compatible with the specialties or equivalencies performed, and shall, at least, be analysis technicians.
2. Technical directors shall be responsible for the operation of the laboratory and for the quality of the activities and exams performed therein, in accordance with the ethical and deontological rules and with the manual of good practises.

### **Article 55 Staff**

Laboratories shall be staffed with duly qualified technical staff, the number of which shall be commensurate with the workload and with the specialties for which they are licensed.

### **Article 56 Collection Stations**

Where operating licenses include the collection of specimen at home or in collection stations, the technical directors shall ensure that duly qualified technicians collect the samples and that the conditioning and transport are undertaken in appropriate thermo-stabilisation conditions.

## **CHAPTER X Radiology and Radiotherapy Units**

### **Section I Facilities and Equipment**

#### **Article 57**

## **Facilities**

Radiology and radiotherapy units shall operate in areas exclusively designed for

**Article 61**  
**Staff**

Radiology and radiotherapy units shall be staffed with duly qualified technical staff, the number of which shall be commensurate with the workload and specialties for which they are licensed.

**CHAPTER XI**  
**Final and Transitional Provisions**

**Article 62**  
**Regulation**

The Minister of Health shall be responsible for the regulation of the present decree-law.

**Article 63**  
**Provisional Clauses**

1. Private health units in operation on the date of the entry into force of the present decree-law shall, within a period of six months to be counted from the date of the entry into force of the present decree-law, require operating licenses, under penalty of closure and application of penalties provided for in Articles 20 and 23.
2. The requirements laid down in the present decree-law shall not be immediately required for private health units that, on the date of the entry into force of the present decree-law, have already been operating for over one year, and the licensing entity shall conduct a case-by-case analysis of the existing conditions, establish a reasonable time frame to adjust to the legally required conditions, or propose its acceptance to the Minister of Health in a judicious and reasoned manner.

**Article 64**  
**Entry into Force**

The present decree-law shall enter into force eight months after its publication.

Approved by the Council of Ministers on 15 November 2004.

The Prime Minister

[Signed]  
Mari Bim Amude Alkatiri

The Minister of Health

[Signed]

Rui Maria de Araujo

Promulgated on 23 November 2004.

To be published.

The President of the Republic

[Signed]

Kay Rala Xanana Gusmao