

NEW LEGAL REGIME FOR HEALTH CARE UNITS

PUBLIC LAW

On 1 September 2014, Decree-Law no. 127/2014, 22 August, entered into force, revising the **legal regime that regulates the opening, modification, and operation of health care units**.

The main novelty of this law is the fact that this regime is applicable not only to private health care units, **but also to public health care units, which is to say units owned by public entities** (integrated into the National Health Care Service) **and Private Social Charity Institutions (IPSS)**¹, therefore, creating a **single legal regime that combines the rules for the opening, operation and modification of every health care unit**, independently of its “*name, legal nature, or the ownership of the unit*”.

The **type of health care unit** will be defined according to the ordinance by the member of the Government responsible for health, as each type will be subject to technical operational requirements.

In the case of health care units integrated into the National Health Care Service and in what concerns IPSS, the assessment of the technical operational requirements is made by issuing a **declaration of conformity** in terms to be defined by the ordinance.

The opening and operation of **private health care units** is subject to **licensing**, which can be obtained by presenting a **previous communication** (simplified procedure) or through the **ordinary procedure**.

The **simplified licensing procedure** is initiated with the electronic submission of a **declaration of responsibility** of the Health Care Regulatory Entity (ERS) Licensing Portal, stating the “*integral compliance with the required operational requirements*” of the actual activity to be licensed. The notice of reception of such declaration is regarded as the license.

¹ The IPSS that provide continuous health care services integrated into the National Net of Continuous Health Care Services, are excluded from the scope of Decree-Law no. 127/2014.

The main novelty is the creation of a single legal regime for health care units, whether they are public or private

As provided in Decree-Law no. 127/2014, the following types of units are subject to a simplified procedure without prejudice to others defined by the ordinance:

- i) Dental Clinics and Offices;
- ii) Medical Clinics and Offices;
- iii) Nursing Centers;
- iv) Physical and rehabilitation units;
- v) X-Ray units.

The **ordinary licensing procedure** initiates with the online filing of a form at the Licensing Portal, available on the ERS website, accompanied by the necessary documents, as provided in Article 5, paragraph 3, of this law.

Among those documents, we find the **certificate of compliance with the licensing requirements**, issued by an external and ERS recognized entity, which waives the need of inspection by the ERS. In case the licensing request is not filed with the above mentioned certificate, an inspection takes place.

Under the terms of this legal regime, the decision of the ERS regarding the license request shall take place within **30 days counting from i) the submission of the licensing request, accompanied by the certificate or ii) from the inspection.**

If no decision is issued within 30 days from the licensing request with the certificate of compliance or within 60 days from the above mentioned request, in the event the certificate of compliance is not presented, **the license is deemed approved.**

One last note about the pending procedures and the units licensed in accordance with the previous legal regime.

Regarding the **pending licensing procedures** at the time of entry into force of Decree-Law no. 127/2014, they shall be transferred to the ERS which will conclude the procedure, giving note of that fact to interested parties. The previous formalities and decisions made in the procedure shall be preserved and the final decision is made on the grounds of the previous legal regime.

As for licensed health care units, their licenses remain valid, notwithstanding the necessary **compliance with the provisions of Decree-Law no. 127/2014 within the period of five years.**

The assessment of the technical operational requirements of public health care units is made by issuing a declaration of conformity

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The Regional Health Care Administration shall forward to the ERS, within 30 days from the entry into force of Decree-Law no. 127/2014, the verification documents of every license issued in the scope of the previous legal regime. Failure to comply with the deadline will determine that the holders of the license are required to submit to the ERS evidence of those licenses.

Contacts

Fernanda Matoso | fmatoso@mlgts.pt
Rui Ribeiro Lima | rrlima@mlgts.pt



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ASSOCIADOS
SOCIEDADE DE
ADVOGADOS

LISBON

Rua Castilho, 165
1070-050 Lisbon
Telephone: (+351) 213 817 400
Fax: (+351) 213 817 499
mlgtslisboa@mlgts.pt

Luanda, Angola (in association)
Angola Legal Circle Advogados

PORTO

Av. da Boavista, 3265 - 5.2
Edifício Oceanvs – 4100-137 Porto
Telephone: (+351) 226 166 950
Fax: (+351) 226 163 810
mlgtsporto@mlgts.pt

Maputo, Mozambique (in association)
Mozambique Legal Circle Advogados

MADEIRA

Avenida Arriaga, 73, 1º, Sala 113
Edifício Marina Club – 9000-060 Funchal
Telephone: (+351) 291 200 040
Fax: (+351) 291 200 049
mlgtsmadeira@mlgts.pt

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