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NEW LEGAL REGIME FOR OPENING, FUNCTIONING AND MODIFICATION OF PRIVATE HEALTHCARE UNITS

PUBLIC LAW

UNIFIED REGULATION FOR THE LICENSING OF PRIVATE HEALTHCARE UNITS

On October 6th, Decree-Law number 279/2009 was published, setting out the new legal regime for opening, functioning and modification of private healthcare units.

This new legal regime now unifies and consistently regulates the licensing of all private healthcare units, thus revoking all other legislation concerning the licensing procedure of private healthcare units, according to their specific activities.

Under the terms of Decree-Law number 279/2009, a **private healthcare unit** is an establishment that operates outside the National Healthcare Service, providing healthcare services, with or without lucrative intent, with no bearing on its designation, legal nature or license holder. This regulation notwithstanding, the legal regime applicable to private healthcare units owned by voluntary organisations shall be defined by specific legislation.

The type of healthcare services to be provided in these private units will also be the object of ministerial order from the member of Government responsible for health issues, as will the identification of the technical requirements that must be observed for the functioning of those units.

According to article 2 of Decree-Law number 279/2009, the exploration of a private healthcare unit depends on obtaining a **license** issued by the competent Regional Health Administration (ARS), and **registering** it at the Health Regulatory Entity (ERS), under the terms of Decree-Law number 127/2009, May 27th, without prejudice of the compliance with the procedures foreseen on the Legal Regime for Land Development and Construction (Decree-Law number 555/99, de December 16th), in what concerns urban operations.

One of the significant provisions in this new legal regime is the fact that should any of these private healthcare units provide several types of health services, they will only require **one license**, obtained through the procedure foreseen for the most demanding type of control.

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The licensing procedure is initiated with the **electronic submission of a form** (license request), available on the internet sites of the ARS and the ERS, which has to be accompanied by the documents foreseen in article 4 of Decree-Law number 279/2009, as well as in the above mentioned ministerial orders.

License approval by tacit consent in case no decision is issued within the legal period.

Pursuant to that phase, a **survey** is scheduled to occur within 30 days after the license request, bearing in mind that the ARS must decide within 30 days from the survey. In the event no decision is issued within that period, **the license is approved by tacit consent**.

On other significant provision is the **simplified licensing procedure** for private healthcare units that provide a given type of health services that are to be defined by ministerial order. Nevertheless, Decree-Law number 279/2009 already identifies those types of health services that are subjected to this form of procedure:

- a) Medical and dental clinics;
- b) Nursing centres;
- c) Physiotherapy units;
- d) Pathological anatomy and clinical pathology laboratories.

Simplified licensing procedure is foreseen.

The simplified licensing procedure consists on filling out a statement, available on the ARS and ERS website, in which the petitioner states that he will comply with all the mandatory requirements for the activity he intends to pursue or is pursuing.

The modifications to the license, namely the enlargement or alteration of the unit, as well as the modification of the license holder, or any other significant change to the license, is subjected to a **communication** from the holder to the competent licensing authority within 30 days.

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All other regulations foreseen in Decree-Law number 279/2009 must be approved within 90 days of its entry into force, which has occurred on **October 11th, 2009**. Despite this fact, the mandatory technical requirements will only be enforceable upon publication of the ministerial orders that define the type of services to be provided by the private healthcare units.

Pending licensing procedures may be subject to this new regime.

Finally, we would like to point out that **pending licensing procedures for private healthcare units**, upon entry into force of this new legislation, may be subject to its dispositions should the petitioner request so to the competent authority.

As to the **private healthcare units that already possess the necessary license**, those will remain valid and in effect, as long as no significant changes occur or until a survey by ARS.

The **private healthcare units that are not licensed** will have one year from the entry into force of Decree-Law number 279/2009 to comply with its provisions.

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