



Installation of Heavy Medical Equipment

Decree-Law 110/2024 of December 19 established the rules for the installation and commissioning of heavy medical equipment.

The approval of this legislation is part of the regime previously defined by Decree-Law no. 95/95, of May 9, and Council of Ministers Resolution no. 61/95, of June 28, which made the installation of heavy medical equipment subject to prior authorization from the member of the government responsible for the health area and defined ratios of equipment per inhabitant.

We therefore highlight the following aspects that Decree-Law 110/2024 of December 19 establishes:

Heavy medical equipment refers to devices used for diagnostic and therapeutic purposes that are subject to regular quality controls, require specialized human resources whose exposure to potential occupational hazards is monitored where applicable, and meet the following conditions:

- a) It is fixed equipment with a specific installation inherent to its use;*
- b) They have physical characteristics that imply that there is no specific and licensed infrastructure for their operation.*

2. Prior authorization vs. Prior notification

The need to obtain prior authorization for the installation of heavy medical equipment will now only apply to public sector entities.

Conversely, the installation of heavy medical equipment by private and social sector entities only requires prior notification to the member of the government responsible for health.

Prior authorization and notification are electronic and follow a form to be approved by the Central Administration of the Health System, I.P. (ACSS, I.P.) and made available on its website.

Failure to comply with the duty to obtain prior authorization or notification constitutes an administrative offense punishable by a fine of €1,000 to €3,740 if the perpetrator is a natural person, and €1,000 to €44,000 if the perpetrator is a legal person.

3. Coverage of the national territory

In order to ensure adequate coverage of the national territory, the installation of heavy medical equipment have to comply with the ratios to be defined by Administrative Ruling of the member of the Government responsible for the health area.

"Call first, save lives"

On 19 December, a set of Administrative Rulings were approved with the aim of extending the "Call first, save lives" project to a number of Local Health Units (LHU), in order to develop proximity responses to emergency care needs.

In this context, the following rules are defined for referral, access to emergency services and referral to primary health care:

1. Referral

Access to hospital healthcare within the National Health Service (SNS) must be preceded by a referral via one of the following means:

- a) Urgent Patients Guidance Center (CODU-INEM);
- b) SNS 24 - National Health Service Contact Center (SNS24);
- c) Primary Health Care (PHC);
- d) Doctor, with signed clinical information;
- e) Another health institution, public, private or social.

2. Access to emergency services

The administrative services must provide a means of contacting the SNS24 for users who come to the hospital emergency services (ER), by making a telephone available on site.

When the patient is not referred through the SNS24, namely due to refusal by the user, they are guaranteed registration in the ER and respective triage according to the Manchester Triage (MT) system, or the system adapted for use in pediatrics.

Patients who are triaged as "blue" or "green" are not seen in the ER, provided that, depending on their clinical condition, they are guaranteed preferential referral to the PHC or to a consultation/day hospital in the institution in which the ER is located, by effectively scheduling an appointment for the same day or the following day, without prejudice to the possibility of adopting other clinical care alternatives for acute situations of lesser complexity and clinical urgency, aimed at caring for non-urgent or less urgent patients.

Notwithstanding this, users who are triaged "blue" or "green" must be evaluated in the ER, in the case of pregnant women, bedridden users or those in wheelchairs who cannot be mobilized by their own means, or whose clinical condition falls within any of the situations listed in the above-mentioned Administrative Rulings.

3. Referral to Primary Health Care

Users who need to be seen in the PHC or in a place with clinical care competence for acute situations of less complexity and clinical urgency should be directed to the PHC:

- a) By the respective family health unit, in case of registered users;
- b) By inclusion in an additional portfolio of Family Health Units (FHU), in other complementary services or at a location to be contracted by the LHU, in the case of non-registered or sporadic users.

If you have any doubts or queries on this matter, please do not hesitate to contact the Health Law team at pbbr - Sociedade de Advogados, SP, RL.

Contacts:

Rita Roque de Pinho – rita.pinho@pbbr.pt

Ana Guedes Machado – ana.machado@pbbr.pt