

## **Law No 13021, of August 8, 2014**

Disposes about the practice and inspection of pharmaceutical activities.

### **Chapter I**

#### **Preliminary Provisions**

Article 1. The provisions of this law rule the actions and services of pharmaceutical assistance, performed, singly or jointly, on a permanent or eventual basis by a legal person or a natural person under public or private law.

Article 2. It is understood as pharmaceutical assistance the cluster of pharmaceutical assistance services which aims at ensuring integral therapeutic assistance, promotion, protection and recovery of health, in either public or private pharmaceutical establishments that provide medicine as an essential product and seek for easy access as well as its rational use.

Article 3. The Pharmacy is a service provision unit in charge of providing pharmaceutical and healthcare assistance along with individual and public sanitary orientation, including drug manipulation and/or dispensation of magistral drug, officinals and pharmacopoeic or industrialized products, cosmetics, pharmaceutical products or related ones.

Sole Paragraph: Pharmacies will be classified in accordance to their nature, as follows:

- I- Pharmacies with no drug manipulation activities or drugstores: Dispensation establishment, drug and medicine trading as well as commerce of related products in their original packages.
- II- Pharmacies with drug manipulation activities: drug manipulation establishment of magistral and officinal products, drug and medicine trading, and similar ones, encompassing the products of dispensation and the ones of exclusive service in a hospital unit or of any other equivalent medical assistance.

Article 4. It is the responsibility of the public authorities to ensure pharmaceutical assistance, according to the principles and guidelines of the Unified Health System (SUS), universality, equity and correctness.

### **Chapter II**

#### **REGARDING PHARMACEUTICAL ACTIVITIES**

Article 5. Within the scope of pharmaceutical assistance, pharmacies of any nature require, mandatorily, for their proper functioning, the responsibility and technical assistance of pharmacists qualified and certified by law.

### **Chapter III**

#### **REGARDING PHARMACEUTICAL ESTABLISHMENTS**

##### **Section 1**

## Regarding Pharmacies

Article 6. For the proper functioning of pharmacies of any kind, it is required the authorization and licensing from the competent authority, aside from the following demands:

- I- presence of a pharmacist during the whole hours of operation;
- II- convenient location, under sanitary conditions.
- III- having the necessary equipment to ensure suitable conservation of immunobiologicals; and
- IV- having equipment and accessories which fulfill the technical requisites established by the health surveillance system.

Sole Paragraph. Considering the provisions of paragraphs 3 and 6 of article 1 of the Complementary Law No. 123, of December 14, 2006, the provisions of article 15 of Law No. 5991, of December 17, 1973, apply to pharmacies that are characterized as micro pharmacies and small business in the form of Supplementary Law No 123, 2006. (Included by Provisional Measure (MP) No. 653, 2014) (Validity)

Article 7. For immediate care, pharmacies of any nature should be able to have medicine, vaccines and serums which can attend the needs of the epidemiological profile in their regions.

Article 8. The pharmacy exclusive of a hospital or similar unit is oriented exclusively towards the care of its users.

Sole Paragraph: It is applicable to the pharmacies to which the caput refers, the same legal demands designated to non-exclusive pharmacies, as far as facilities, equipment and the pharmacists' technical performance are concerned, along with the registration in the Brazilian Pharmacy Regional Council.

Article 9. (VETOED).

## Section II

### Regarding Responsibilities

Article 10. The pharmacist and the owners of the pharmaceutical establishments are to work in solidarity, making an effort to promote the rational use of the medicines.

Article 11. The owner of the pharmacy will not be able to disallow or disregard the technical orientations established by the pharmacist.

Sole paragraph. It is the responsibility of the pharmaceutical establishment to provide conditions which are adequate to the perfect development of the pharmacist's professional activities.

Article 12. In face of the pharmacist's leaving his position, it is determined that the establishments hire a new professional within a 30-day period, in accordance to the provisions in Law No 5991, of December 17, 1973 and Law No. 6437 of August 20, 1977.

Article 13. In the exercise of their functions, the pharmacists are in charge of:

- I- Notifying healthcare professionals, competent sanitary agencies, as well as the industrial laboratory, of side effects, adverse reactions, intoxications, either voluntary or not, pharmacodependence, noticed and registered while practicing pharmacosurveillance;
- II- Organizing and keeping registration updated with techno-scientific data on drugs and medicines available at the pharmacy;
- III- Proceeding to the pharmacotherapeutic patients' follow-ups, whether they are admitted or not, in a hospital or ambulatory establishment, be it of public or private nature;
- IV- Establishing protocols on medicine pharmacological surveillance, pharmaceutical inputs and correlatives, aiming at ensuring its rational use as well as therapeutical safety and efficacy.
- V- Establishing the pharmacotherapy profile during the patient systematic monitoring by means of elaboration, filling up and interpreting pharmacotherapy charts.
- VI- Providing pharmaceutical orientation, with the intent to clarify and explain to the patient the risk-benefit assessment, the conservation and usage of drugs and medicines inherent to the therapy, the drug interactions, and the importance of correct handling.

Article 14. In order for safety and efficacy to be assured, it is the pharmacist's duty to consider technical and legal aspects on the prescription when dispensing medicine.

#### Chapter IV

#### REGARDING INSPECTION

Article 15. (VETOED).

Article 16. The pharmacy inspector is neither allowed to perform activities other than his inspecting attributions, nor should he or she be the technical manager, nor a participant in the association of pharmaceutical establishments.

#### Chapter V

#### REGARDING GENERAL AND TRANSITIONAL PROVISIONS

Article. 17. (VETOED).

Article 18. (VETOED).

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