P.R. Laws tit. 20, § 407

§ 407. Definitions

For the purposes of this chapter, the following terms and phrases shall have the meaning stated below:

(a) Administration of drugs.— An action through which any drug dose is used or applied in or to a human or animal by injection, inhalation, ingestion, or any other means, with the authorization and in accordance with the indications or prescription made by a physician, odontologist, dentist, podiatrist, or in the case of animals, by a veterinarian authorized to practice his/her profession in Puerto Rico. In the case of vaccination administration to humans, these may be administered by duly certified pharmacists, as provided in this chapter.

(b) Representative agent.— Any person authorized and registered with the Secretary to represent any medication manufacturer or distributor in the marketing thereof, without being involved in the storage, distribution, or dispensation of the same.

(c) Device.— Any object, article, or instrument designed, prepared or made to be used in the diagnosis, cure, mitigation, treatment, or prevention of diseases of a human being or an animal, pursuant to the laws of Puerto Rico and the United States.

(d) Drug cabinet.— Deposit of limited quantities of drugs in institutions, medical offices, or in Category III Ambulance Stations intended solely for their administration to patients in such institution, medical office, or ambulance, or to be used in educational institutions for educational or research purposes, thus prohibiting their dispensing or delivery for their subsequent use by patients. The definition above does not includes [sic] first aid kits or medication kits required by existing federal and state labor laws and regulations, such as the Occupational Safety and Health Act (OSHA) according to the terms required by federal or state legislation. Any drugs in excess to the quantities required by federal or state laws shall be subject to the drug cabinet regulations directed in this chapter.

(e) College of Pharmacists of Puerto Rico.— The quasi-public corporation created with said name by §§ 431—441 of this title, which groups all pharmacists authorized to practice the profession of pharmacy in Puerto Rico.

(f) Compounding.— The preparation, unseasonable mixing, or reconstitution of a drug based on the physician-patient-pharmacist relationship in compliance with the requirements established by the Board of Pharmacy and any other regulatory agencies.

(g) Pharmaceutical care or pharmaceutical assistance.— The practice of the profession of pharmacy centered in the patient and oriented to results that require the pharmacist to work together with the patient and other health care providers, to promote health, to prevent diseases, and ensure that the pharmacotherapy regime of the patient to be safe and effective, with the purpose of contributing to the patient's achievement of an optimum quality of life in terms of his/her health.

(h) Department.— The Department of Health of the Commonwealth of Puerto Rico and all its programs, offices, dependencies, and divisions attached thereto.

(i) Dispensing or dispatch.— The action carried out by a pharmacist of receiving, verifying, evaluating and interpreting a prescription, choosing or compounding, packaging, labeling and delivering of drugs or devices directly to a patient or his/her authorized representative, including providing counseling and advice to the patient on the adequate use thereof. Provided, That the pharmacy technician, the pharmacy technician intern, as well as the pharmacist intern may carry out some of these functions under the supervision of the pharmacist, except for verifying the prescription and orienting the patient. In the case of drugs for animals, these shall be processed in agreement to the provisions of §§ 2951—2969 of this title.

(j) Distribution.— The wholesale sale or distribution of drugs to establishments authorized and registered by the Secretary, as provided by this chapter.

(k) Wholesale medications distributor.— Any person duly authorized and registered by the Secretary who is engaged in the wholesale distribution of prescription drugs to authorized establishments, including but without being limited to manufacturers, repackagers, own or private label distributors, wholesaler drugstores, intermediaries, agents, including manufacturers' and distributors' warehouses, chain drug warehouses, and independent wholesale drug trader, and retail pharmacies that conduct wholesale distributions.

(l) Nonprescription drug wholesaler.— Any person duly authorized and registered by the Secretary for the wholesale sale and distribution of nonprescription drugs, to authorized establishments pursuant to the provisions of this chapter.

(m) Nonprescription drug retailer.— Any person duly authorized and registered by the Secretary for the retail sale of nonprescription drugs, pursuant to the provisions of this chapter.

(n) Veterinary drug retailer.— Any person duly authorized and registered for the wholesale sale of veterinary drugs, as provided by this chapter.

(o) Nonprescription veterinary drug retailer.— Any person duly authorized and registered for the retail sale of nonprescription veterinary drugs, as provided by this chapter.

(p) Drug and pharmacy division.— Administrative unit attached to the Office of the Deputy Secretary for Health Facility Regulation and Accreditation of the Department of Health.

(q) Drug.— Any substance of animal, vegetable, mineral or synthetic origin, or combination thereof, (1) recognized in the official compendium of the United States Pharmacopoeia, the National Formulary, or the Homeopathic Pharmacopoeia of the United States; (2) or intended for use in the diagnosis, cure, mitigation, treatment, or prevention of a disease, injury, or any other condition that affects the health of human beings or other animals; (3) or (other than food) intended to affect or assess the structure or other function of the body of humans or animals; (4) or the component of any of the above.

(r) Wholesaler drugstore.— Any establishment authorized and registered pursuant to this chapter for the wholesale sale [of] drugs, devices, and products, including those related to veterinary medicine.

(s) Patient pharmacy record.— Information of the patient that is electronically collected or otherwise organized to allow pharmacists to identify any drug-related problems and document their interventions and the results obtained for the protection of the health, safety and welfare of the patient.

(t) Pharmacist.— Any person duly authorized pursuant to this chapter to practice the profession of pharmacy in Puerto Rico.

(u) Inspector pharmacist.— A pharmacist official of the Department of Health designated and authorized to oversee compliance with all the requirements established in this chapter by the establishments carrying out any of the activities set forth herein.

(v) Preceptor pharmacist.— A pharmacist authorized by the Board of Pharmacy to supervise the internship training of a pharmacist intern or a pharmacy technician intern.

(w) Head pharmacist.— A pharmacist registered as a head pharmacist in the records of the Department of Health, and who is responsible for overseeing faithful compliance with the provisions of this chapter and any other laws applicable to the manufacture, distribution, and dispensation of drugs in Puerto Rico. In cases of head pharmacists in the pharmaceutical industry, the head pharmacist shall be understood to be the pharmacist in a pharmaceutical enterprise whose name is registered as such in the records of the Department of Health. He/she shall be responsible, as [a] member of a multidisciplinary team, for overseeing faithful compliance with the provisions of this chapter and any other laws applicable to the manufacture, packaging, and distribution of drugs in Puerto Rico.

(x) Pharmacy.— A health service establishment, physically located within the jurisdiction of Puerto Rico, authorized and registered pursuant to the provisions of this chapter, to be engaged in the rendering of pharmaceutical services, that include: dispensation of prescription drugs, nonprescription drugs, devices, and other articles related to health; the rendering of pharmaceutical care, and other services within the pharmacist's functions established by this chapter. Provided, That the pharmacy shall offer the public other legally tradeable products and services business, according to the applicable laws.

(y) Community pharmacy.— Any pharmacy engaged in the rendering of pharmaceutical services to outpatients and the general public.

(z) Institutional pharmacy.— Any pharmacy engaged in the rendering of pharmaceutical services to patients admitted into a health care service institution or facility.

(aa) Pharmaceutical industry.— The industry engaged in the manufacture, marketing, and distribution of drugs.

(bb) Confidential information.— Any information obtained in the pharmacist-patient relation, which is expected not to be released, including the protected health information of the patient.

(cc) Internship.— The practical training period required of a pharmacy intern or a pharmacy technician intern, as authorized by the Board of Pharmacy.

(dd) Pharmacy intern.— A candidate for a pharmacist license authorized by the Board of Pharmacy to receive practical training under the direct and immediate supervision of a preceptor pharmacist.

(ee) Pharmacy technician intern.— A candidate for a certificate of pharmacy technician authorized by the Board of Pharmacy to receive practical training under the direct and immediate supervision of a preceptor pharmacist.

(ff) Veterinary facility.— A doctor's office, dispensary, office, clinic, or diagnostic and treatment facility, hospital, veterinary outpatient clinic, or any other public or private institution in which veterinarians authorized to practice their profession in Puerto Rico render professional services.

(gg) Board.— The Puerto Rico Board of Pharmacy created by this chapter.

(hh) Free pharmacy selection.— The right of the patient to select the pharmacy of his/her choice, voluntarily and without pressure from other persons or institutions.

(ii) Manufacture.— The production, preparation, and processing of drugs, whether directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis to be used as drugs. It includes any packing or repackaging of the substances or labeling of its container.

(jj) Medication or medicine.— Any drug intended for use by humans or other animals in appropriate doses.

(kk) Prescription drug or medication.— Any drug that is required under the Puerto Rico or the United States laws to be dispensed by prescription, which shall be dispensed by a pharmacist in a pharmacy duly authorized and registered by the Secretary of Health; or in the case of veterinary drugs, these may also be dispensed by a veterinarian duly authorized to practice his/her profession in Puerto Rico.

(ll) Nonprescription drug or medication.— Any drug that, in accordance with the laws of Puerto Rico or the United States, may be dispensed without a prescription.

(mm) Bioequivalent drug.— Those drugs classified by the Food and Drugs Administration (FDA) as therapeutically equivalent since they contain the same active ingredients, have the same strength, dosage and form of administration; and have comparable bioavailability.

(nn) Radioactive drug or radiopharmaceutical.— A drug or medication that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons, including any non-radioactive reagent kit or nuclide generator that is intended to be used in the preparation of such substance

(oo) Veterinary drug.— Any drug indicating in its label that it is intended exclusively for use in the diagnosis, prevention, cure, relief, or treatments of diseases in animals.

(pp) Prescription veterinary drug.— Any drug indicating in its label that may be dispensed solely and exclusively by means of an order or prescription issued by an authorized veterinarian.

(qq) Patient.— Natural person who is the final consumer of the pharmaceutical services, or in the case of animals, is that with which a duly licensed veterinarian maintains a valid veterinarian-client-patient relationship under §§ 2951—2969 of this title.

(rr) Person.— Any natural or juridical person, regardless of its denomination or manner in which it is constituted.

(ss) Prescribing professional.— Medicine doctor, physician, odontologist, dentist, podiatrist, or veterinarian authorized to practice the profession in Puerto Rico or any other United States jurisdiction or territory, who issues a prescription or order so that the patient with whom he/she maintains a valid professional relationship receives the drugs.

(tt) Biological product.— A drug derived from live organisms and its by-products, such as serums, vaccines, antigens, antitoxins and others.

(uu) Protocol.— Document to execute the written agreement between the physician or group of physicians and the pharmacist, following the guidelines established by the Board, authorizing the pharmacist to initiate or modify the pharmacotherapy of the patient to collaboratively manage the same.

(vv) Radiopharmacy.— Any pharmacy authorized and registered by the Secretary of Health engaged in the preparation and dispensation of radioactive drugs.

(ww) Prescription.— Original written order, issued and signed or generated, and electronically transmitted by the prescribing professional in the regular and lawful course of his/her professional practice in Puerto Rico, or any other United States jurisdiction or territory, for dispensing certain drugs or devices in compliance with the provisions of this chapter and the laws of the state of origin thereof. Likewise, in order to be lawfully dispensed, such prescription shall meet the statutory requirements of our jurisdiction. It shall be the obligation of the physician issuing the same to fulfill the professional responsibility of a true doctor- patient relationship. Provided, that both, prescriptions issued by physicians authorized to practice in Puerto Rico and prescriptions issued by physicians authorized to practice in any state or territory of the United States of America, in accordance with the provisions of §§ 2101 et seq. of Title 24, known as the "Controlled Substances Act", may be refilled in Puerto Rico with the previous authorization of the prescribing professional.

(xx) Pharmacy counter.— Space or area in a pharmacy devoted to dispensing prescription drugs and devices.

(yy) Doctor-patient relationship.— It is that action through which a physician, as described in subsection (vv) above, assumes or has assumed the responsibility of performing an evaluation or clinical determination regarding the patient's health. He/she determines the need for medical treatment based on the general or preliminary diagnosis of the medical condition

which calls for said treatment and proves to be available for follow-up treatment in case of an adverse reaction or failure in the therapeutic regime. Being it understood that a valid professional relationship may not be established solely by phone or electronic means.

(zz) Representative or authorized representative.— Legal guardian, relative, or natural person of legal age, designated and identified, freely and willingly, by the patient to personally receive the pharmaceutical services on behalf of the patient, thus complying with the laws and regulations applicable to the confidentiality and privacy of the patient's protected health information. In the case of animals, it shall be understood as the representative or authorized representative of the holder of the prescription.

(aaa) Secretary or Secretary of Health.— The Secretary of the Department of Health of the Government of Puerto Rico.

(bbb) Pharmacy technician.— Any person duly authorized pursuant to this chapter to practice the occupation of pharmacy technician in Puerto Rico. It includes any person, who at the time of the approval of this act is authorized by the Board of Pharmacy to practice the occupation of pharmacy assistant, pursuant to Act No. 282 of May 15, 1945, as amended.

(ccc) Electronically generated and transmitted prescription.— Means any electronically generated and transmitted prescription issued by a prescribing professional to a pharmacy freely selected by the patient, through a device that authenticates the electronic signature of the prescribing professional and guarantees the security of transmittal according to the applicable rules, laws, and regulations. For the purposes of this chapter, the electronically generated and transmitted prescription shall also be known as electronic prescription and shall constitute an original order, thus an order with a handwritten signature shall not be required.

(ddd) Electronic signature.— Group of data in electronic format contained in a message, document or transaction attached to or logically associated with such message, document or transaction that may be used to identify the signatory, and indicate that the signatory approves and recognizes the information contained in the message, document or transaction.

(eee) Vaccine.— Means a preparation of living, inactive or dead microorganisms, portions thereof or specially prepared antigen that upon administration stimulate[s] people's immunity to a disease.

(fff) Vaccination or immunization.— Means the administration of vaccines by a duly certified pharmacist, as provided in this chapter.

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