

Louisiana Revised Statutes of 1950

Title 37 – Professions and Occupations

Chapter 14 – Pharmacy Practice Act

[Editor's Note: The Louisiana Pharmacy Practice Act was substantially revised and reorganized under the authority of Act 767 of the 1999 Louisiana Legislature. Subsequent amendments are noted herein.]

Part A. General Provisions

§1161. Short title

This Chapter shall be known as the "Louisiana Pharmacy Practice Act".

§1162. Legislative declaration

The practice of pharmacy in the state of Louisiana is declared a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest. Therefore, any rule or regulation adopted relative to pharmacists and the operations of pharmacies, including any amendment, modification, or repeal thereof, shall be adopted as provided by the Administrative Procedure Act and shall be effective only upon approval by the respective oversight committees having jurisdiction over matters relative to pharmacists and the operation of pharmacies. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this Chapter, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy. This Chapter shall be liberally construed to carry out these objectives and purposes.

§1163. Statement of purpose

It is the purpose of this Chapter to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy; the licensure of pharmacists; and the licensure, permitting, certification, registration, control, and regulation of all persons or sites, in or out of this state that sell drugs or devices to consumers and/or patients or assist in the practice of pharmacy, within the state.

§1164. Definitions

As used in this Chapter, the following terms have the meaning ascribed to them by this Section:

(1) "*Administer*" or "*administration*" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

(2) "*Approved college of pharmacy*" means an educational institution approved by the board which meets one of the following additional criteria:

(a) A college or school of pharmacy which is accredited by the Accreditation Council for Pharmacy Education.

(b) A foreign college or school of pharmacy which is listed in the World Health Organization's "World Directory of Schools of Pharmacy" and whose graduate has attained educational equivalency status through a mechanism established by the board.

(Amended by Act 164 of 2006 Legislature, effective August 15, 2006; further amended by Act 112 of 2013 Legislature, effective August 1, 2013)

(3) "*Automated medication system*" includes, but is not limited to, a mechanical system that perform operations or activities, other than compounding or administration, relative to the storage, packaging, or delivery of medications, and which collects, controls, and maintains all transaction information. An automated medication system may be profile driven, non-profile driven, or a combination of both.

(a) "*Profile driven*" system requires that medication orders/prescriptions be reviewed by the pharmacist for appropriateness, dosage, and contraindications prior to, or concomitantly with, being entered into the system, and before access is allowed into the system for medication administration.

(b)(i) "*Non-profile driven*" system does not require prior or concomitant pharmacist review of medication orders/prescriptions in order to gain access to the system for medication administration. A non-profile driven system may include, but is not limited to, a night drug cabinet, emergency drug kit, or floor stock/first dose cabinet.

(ii) "*Floor stock/first dose cabinet*" is a medication storage device, which shall be used by personnel, authorized by a protocol established by the pharmacist-in-charge, to gain access to doses as needed and first doses in patient-care areas. In addition, a floor stock/first dose cabinet may be used to store medications in such specialty areas including, but not limited to, an emergency room, surgery suite, and endoscopy suite.

(4) "*Board*" means the Louisiana Board of Pharmacy.

(5) "*Compounding*" means the preparation, mixing, assembling, packaging, or labeling of a drug or device by a pharmacist for his patient as the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice, or including the preparation of drugs or devices in anticipation of prescription drug orders to be received by the compounding pharmacist based on routine, regularly observed prescribing patterns. Compounding does not include the compounding of drug products that are essentially copies of a commercially available product.

(6) "*Confidential information*" means information accessed, maintained by, or transmitted to a pharmacist in the patient's records or which is communicated to the patient as part of patient counseling, which is privileged and may be released only to the patient or, to those practitioners, other authorized health care professionals, and other pharmacists when, in a pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other persons or agencies authorized by law to receive such confidential information regardless of whether such information is in the form of paper, preserved on microfilm, or is stored on electronic media.

(7) "*Costs*" is a monetary amount assessed to cover administrative expenses, including but not limited to licensure, permitting, certification, registration, and the investigation and prosecution of a disciplinary action.

(8) "*Deliver*" or "*delivery*" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

(9) "*Device*" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: Federal or State law requires dispensing by or on the order of a physician" and/or "Rx Only", or any other designation required under federal law.

(10) "*Dispense*" or "*dispensing*" means the interpretation, evaluation, and implementation of a prescription drug order, including the preparation and delivery of a drug or device to a patient or patient's agent in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. "Dispense" necessarily includes a transfer of possession of a drug or device to the patient or the patient's agent.

(11) "*Distribute*" or "*distribution*" means the delivery of a drug or device other than by administering or dispensing.

(12) "*Drug*" means: (a) any substance recognized as a drug in the official compendium, or supplement thereto, designated by the board for use in the diagnosis, cure, mitigation, treatment or prevention of diseases in humans or animals, (b) any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals, or (c) any substance other than food intended to affect the structure or any function of the body of humans or other animals.

(13) "*Drug regimen review*" means and includes, but is not limited to, the following activities:

(a) Review of the prescription drug order and patient record for: [i] known allergies, [ii] therapy contraindications, [iii] dose and route of administration, and [iv] directions for use;

(b) Review of the prescription drug order and patient record for duplication of therapy;

(c) Review of the prescription drug order and patient record for interactions; and

(d) Review of the prescription drug order and patient record for proper utilization including over- or under- utilization, and optimum therapeutic outcomes.

(14) "*Electronic transmission*" means transmission of information in electronic form or the transmission of the exact visual image of a document by way of electronic equipment.

(15) "*Emergency drug kit (EDK)*" for long-term care facilities (LTCF) or other board approved sites, other than a hospital, means a drug kit containing designated drugs which may be required to meet the immediate therapeutic emergency needs of a resident or patient.

(16) "*Equivalent drug product*" means either of the following:

(a) A drug product that has been rated as a pharmaceutical equivalent by the United States Food and Drug Administration (FDA) and has the same established name, active ingredients, strength or concentration, dosage form, and route of administration and which is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendial or other applicable standards such as strength, quality, purity, and identity, but which may differ in characteristics such as shape, scoring, configuration, packaging, excipients including colors, flavors, preservatives, and expiration time.

(b) A biological product that is either one of the following:

(1) Deemed by the United States Food and Drug Administration as meeting the standard set forth in 42 U.S.C. 262(k)(4) and rated as interchangeable in the *Lists of Licensed Biologic Products with Reference Product Exclusivity and Biosimilarity and Interchangeability Evaluations*, sometimes referred to as the "Purple Book", or its successors.

(2) Rated therapeutically equivalent by the United States Food and Drug Administration as set forth in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, sometimes referred to as the "Orange Book", or its successors.

(Amended by Act 391 of 2015 Legislature, effective August 1, 2015.)

(17) "*Final checks of work*" is the requirement that only a pharmacist supervises and releases the completed product prepared by a pharmacy technician.

(18) "*Hospital pharmacy*" means a pharmacy department located in a hospital licensed under R.S. 40:2100 et seq. For the purposes of this Chapter a hospital pharmacy is one example of a primary care treatment modality pharmacy.

(19) "*Infusion pharmacy*" means a pharmacy that provides prepared solutions for direct administration to a patient in a private residence, long term care facility, or hospice setting by means of irrigation, enteral, parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion.

(20) "*Institutional facility*" means any organization whose primary purpose is to provide a physical environment for a patient to obtain health care services, including but not limited to a:

- (a) Hospital pharmacy.
- (b) Convalescent home.
- (c) Nursing home.
- (d) Extended care facility.
- (e) Mental health facility.
- (f) Rehabilitation center.
- (g) Psychiatric center.
- (h) Developmental disability center.
- (i) Drug abuse treatment center.
- (j) Family planning clinic.
- (k) Penal institution.
- (l) Hospice.
- (m) Public health facility.
- (n) Athletic facility.

(21) "*Institutional pharmacy*" means that physical portion of an institutional facility where drugs, devices, and other materials used in the diagnosis and treatment of injury, illness, and disease are dispensed, compounded, and distributed and pharmacy primary care is provided; and is permitted by the board and is devoted exclusively to providing professional services to a patient in that institutional setting other than a hospital.

(22) "*Labeling*" means the process of preparing and affixing a label to any drug container exclusive, however, of the labeling by a manufacturer, packer, or distributor of a non-prescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law or regulation.

(23) "*Long term care facility*" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to a residential patient, including but not limited to health care facilities licensed by the Department of Health and Hospitals.

(24) "*Manufacturer*" means a person who manufactures drugs and includes a labeler, primary distributor, or person who prepares drugs in dosage form by mixing.

(25) "*Manufacturing*" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical or biological synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, and the promotion and marketing of such drugs or devices. Manufacturing also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

(26) "*Medical order*" means a lawful order of a practitioner that may or may not include a prescription.

(27) "*Non-prescription drug*" means a drug that may be sold without a prescription and that is labeled for use by the consumer in accordance with the federal and state laws and regulations.

(28) "*Out-of-state pharmacy*" means a pharmacy located outside this state.

(29) "*On-site facility*" means and refers to the location of a building that houses a board permitted pharmacy.

(30) "*Off-site facility*" means and refers to the location of a building that houses a licensee of the Department of Health and Hospitals, but which does not house a board permitted pharmacy.

(31) "*Patient counseling*" means the communication by a pharmacist of information, as defined by the regulations of the board, to the patient or caregiver, in order to ensure proper use of drugs and devices.

(32) "*Permit*" means the grant of authority by the board to any person authorizing the practice of pharmacy at a site.

(33) "*Person*" means an individual, corporation, partnership, association, or any other legal entity, including government.

(34) "*Pharmacist*" means an individual currently licensed by the board to engage in the practice of

pharmacy in the state.

(35) "*Pharmacist-in-charge*" means a pharmacist currently licensed by the board who accepts responsibility for the operation of a pharmacy in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs, and who is personally in full and actual charge of such pharmacy and personnel.

(36) "*Pharmacy*" means any place located within this state where drugs are dispensed and pharmacy primary care is provided, and any place outside of this state where drugs are dispensed and pharmacy primary care is provided to residents of this state.

(37)(a) "*Pharmacy collaborative drug therapy management*" means that practice whereby a pharmacist or pharmacists have, on a voluntary basis, agreed to manage the disease-specific drug therapy of a patient under written protocol, working in conjunction with a physician licensed to practice medicine by the Louisiana State Board of Medical Examiners. Pharmacy collaborative drug therapy management does not include the substitution by the pharmacist of a product that is not an equivalent drug product to the product originally prescribed by the physician or practitioner without the explicit consent of the physician or practitioner. Any pharmacy collaborative drug therapy management protocol shall adhere to rules and regulations promulgated by the board.

(b)(i) The Louisiana State Board of Medical Examiners and the Louisiana Board of Pharmacy shall initiate the rulemaking process in accordance with the provisions of the Administrative Procedure Act by publishing their respective notices of intent no later than one hundred twenty days following the effective date of this Subparagraph.

(ii) If both boards have not initiated the rulemaking process in accordance with the provisions of the Administrative Procedure Act by publishing their respective notices of intent by one hundred twenty days following the effective date of this Subparagraph, then the boards shall appoint a committee composed of three physicians and three pharmacists, the physicians by the Louisiana State Board of Medical Examiners and the pharmacists by the Louisiana Board of Pharmacy. This committee shall complete the drafting process no later than one hundred eighty days following the effective date of this Subparagraph.

(iii) If the boards have not initiated the rulemaking process in accordance with the provisions of the Administrative Procedure Act by publishing their respective notices of intent by one hundred eighty days following the effective date of this Subparagraph, then the Louisiana Board of Pharmacy shall have the authority to promulgate the rule required in R.S. 37:1164(37) independently of the Louisiana State Board of Medical Examiners.

(Amended by Act 627 of 2006 Legislature, effective August 15, 2006)

(38) "*Pharmacy primary care*" means bringing health care as close as possible to where people live and work and may constitute a portal of entry into the continuing health care process in an effort to enhance optimum therapeutic outcomes.

(39) "*Pharmacy intern*" means an individual who is:

(a) Engaged in the practice of pharmacy while under the direct and immediate supervision of a pharmacist for the purpose of obtaining practical experience for licensure as a pharmacist and is satisfactorily progressing in a board-approved college of pharmacy.

(b) A graduate of a board-approved college of pharmacy or a graduate who has established educational equivalency through a program approved by the board.

(c) A qualified applicant awaiting examination for licensure.

(d) An individual participating in a residency or fellowship.

(40) "*Pharmacy technician*" means an individual who assists in the practice of pharmacy under the direct and immediate supervision of a licensed pharmacist and is certified to do so by the board.

(41) "*Practice of pharmacy*" or "*practice of the profession of pharmacy*" means and includes the compounding, filling, dispensing, exchanging, giving, offering for sale, or selling, drugs, medicines, or poisons, pursuant to prescriptions or orders of physicians, dentists, veterinarians, or other licensed practitioners, or any other act, service operation or transaction incidental to or forming a part of any of the foregoing acts, requiring, involving or employing the science or art of any branch of the pharmacy profession, study or training.

(42) "*Practitioner*" means an individual currently licensed, registered, or otherwise authorized by the appropriate licensing board to prescribe and administer drugs in the course of professional practice.

(43) "*Preceptor*" means an individual who is currently licensed as a pharmacist by the board, meets certain qualifications as a preceptor as established by the board, and participates in the instructional training of pharmacy interns.

(44) "*Prescription*" or "*prescription drug order*" means an order from a practitioner authorized by law to prescribe for a drug or device that is patient specific and is communicated by any means to a pharmacist in a permitted pharmacy, and is to be preserved on file as required by law or regulation.

(45) "*Prescription drug*" or "*legend drug*" means a drug that is required by any applicable federal or state law or regulation to be dispensed or delivered pursuant only to a prescription drug order, or is restricted to use by practitioners only.

(46) "*Probation*" means a restriction of pharmacy practice for a specified period of time.

(47) "*Reciprocity*" means the acknowledgment and licensure of a pharmacist from another state or jurisdiction pursuant to procedures established by the board.

(48) "*Reprimand*" means a formal reproof of a person for violation of this Chapter or rules and regulations of the board.

(49) "*Reverse drug distributor*" means a person that receives and handles drugs that are expired, discontinued, adulterated, or misbranded, for the purposes of destruction or other final disposition or for return to the original manufacturer of a drug.

(50) "*Revocation*" is the withdrawal of the license, permit, certification, or registration authorized under this Chapter and means that a person under active revocation no longer has the privilege to practice in the state.

(51) "*Significant adverse drug reaction*" means any drug-related incident that may result in serious harm, injury, or death to the patient.

(52) "*Summary suspension*" means the suspension of a license, permit, certification, or registration that requires a person to cease practice immediately pending the results of a hearing.

(53) "*Suspension*" means the withdrawal of the license, permit, certification, or registration to practice pharmacy in the state for a period of time.

(54) "*Warning*" means a written notice issued to a person addressing possible aberrant conduct.

(55) "*Wholesale drug distribution*" means distribution of legend drugs to other than the consumer or patient, including but not limited to distribution by manufacturers, repackers, own label distributors, jobbers and wholesale drug distributors.

(56) "*Wholesale drug distributor*" means any person who sells legend drugs to other than the consumer or the patient, including but not limited to manufacturers, repackers, own label distributors, jobbers, brokers, agents, and pharmacies.

(57) "*Pharmacy-generated drug*" means a drug made by a pharmacy.

(Added by Act 168 of 2013 Legislature, effective August 1, 2013.)

(58) "*Biological product*" has the meaning assigned by Section 351 of the Public Health Service Act, 42 U.S.C. 262.

(Added by Act 391 of 2015 Legislature, effective August 1, 2015.)

(end of Part A of Chapter 14)