# Louisiana Pharmacy Laws & Rules

A Compilation of State Laws & Rules for Pharmacy Practice

**Edited by Malcolm Broussard** 

2nd Edition ~ August 2024

### **Notices**

The Louisiana Legislature has vested final authority on content and format of state laws with the Louisiana State Law Institute. Further, the legislature has vested final authority on content and format of state rules with the Office of the State Register in the Division of Administration. While every effort has been made to ensure the accuracy of the material in this book, any errors or conflicts shall be resolved in favor of these authorities.

This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is sold and distributed with the understanding that the author, publisher and seller are not engaged in rendering legal, accounting or other professional advice or service. If legal or other expert assistance is required, the services of a competent professional advisor should be sought.

ISBN: 979-8-9900372-1-2

Published August 31, 2024. For updates or new editions, please contact:

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### Introduction

This book contains a selection of state pharmacy laws relevant to the *practice* of pharmacy as well as all of the state pharmacy rules. While the inclusion of the pharmacy practice act, food and drug law, and controlled substance laws are obvious choices, others such as abortion and gender affirming care might not be so obvious. However, those laws contain restrictions on pharmacy practice and are included solely for that reason. Not included in this book are laws relevant to the *business* of pharmacy, such as insurance laws for reimbursement for products and services by private and public payors as well as tax laws for pharmacy products and services.

#### Laws

When the Louisiana Legislature passes a bill and it is signed into law by the governor, the new law is referred to as a legislative act and assigned an act number specific for that legislative session. Unless specified otherwise within the act, legislation enacted during a regular session shall become effective on August 1 of that same calendar year. Legislation enacted during an extraordinary (special) session shall become effective 60 days after the adjournment of that special session, unless specified otherwise within the act. The Louisiana State Law Institute is responsible for adding new laws to the *Louisiana Revised Statutes*.

The <u>Louisiana Revised Statutes</u> is a compilation of all of the laws passed by the state legislature that are currently in effect. The compilation is organized in approximately 54 titles, which are further divided into smaller units as illustrated below. Each paragraph of text is codified. Titles, Subparts, and Chapters are labeled within Arabic numerals, Parts with upper case Roman numerals, and Subchapters with upper case letters. The use of subpart and subchapter headings is optional.

Title 1
Part I
Subpart 1 (optional)
Chapter 1
Subchapter A (optional)

§101. Section

A. Subsection

- 1. Paragraph
  - a. Subparagraph
    - i. Clause
      - (a) Subclause
        - (i) Division

Laws are commonly cited using an abbreviated format, e.g.: R.S. 37:1161, where R.S. refers to *Louisiana Revised Statutes*, followed by a space; 37 refers to the title number, followed by a colon; and 1161 refers to the section number. Where applicable, subsections, paragraphs and further subdivisions may also be included in a citation, separated by parentheses, to identify specific text within the law.

The laws selected for inclusion in this text are presented in numerical sequence by title, chapter and section number. The laws included in this text are current through the 2024 legislative sessions.

### Rules

The Louisiana Legislature has vested final authority for the content and format of all state rules with the Office of the Louisiana Register, housed within the Louisiana Division of Administration. When a state agency intends to promulgate a rule, both the notice of intent to promulgate the rule as well as the notice of the final rule must be printed within the *Louisiana Register* following a process identified within the state's administrative procedure law. The state register is published on the twentieth day of each month. Unless specified otherwise within the notice of the final rule, rules become effective on the day of their publication in the state register. When a final rule is printed in the state register, it is then added to the *Louisiana Administrative Code*.

The <u>Louisiana Administrative Code</u> is a compilation of all of the rules promulgated by all of the state agencies in Louisiana. The code is organized in approximately 35 different titles, which are further divided into smaller units as illustrated above. Each paragraph of text is codified. Titles, Subparts, and Chapters are labeled with Arabic numerals, Parts with upper case Roman numerals, and Subchapters with upper case letters. The use of subpart and subchapter headings is optional.

Rules are commonly cited using an abbreviated format, e.g.: LAC 46:LIII.101, where LAC refers to *Louisiana Administrative Code*, followed by a space; 46 refers to the title number, followed by a colon; LIII refers to the part number, followed by a period; and 101 refers to the section number. Where applicable, subsections, paragraphs, and further subdivisions, separated by periods, may also be included in a citation to identify specific text within the rule.

Title 46 of the <u>Louisiana Administrative Code</u> contains all of the professional and occupational standards. Within Title 46, Part LIII is reserved for pharmacists. All of the rules promulgated by the Louisiana Board of Pharmacy are found within Part LIII of Title 46 and that Part does not contain rules promulgated by any other state agency. The rules included in this text are all of the rules from Part LIII of Title 46; they are presented in numerical sequence by chapter and section number and are current through August 31, 2024.

#### Reader Aids

The appearance of a series of three asterisks centered on a single line (\*\*\*) signifies additional text not relevant to the purpose of this book.

Where a law or rule includes a reference to another law, with or without the use of specific citations, the referenced law or citation is hyperlinked to guide the reader to the referenced law. The few exceptions to the insertion of a hyperlink are noted with explanations and typically include obsolete references; while the reference was accurate when the law or rule was adopted, the referenced law may have been relocated or repealed since the date the subject law or rule was adopted.

While there is no published index, there is a table of contents. The reader is also invited to use the search function embedded in the reader software. Finally, all of the section headings are bookmarked.

# **Updates to Previous Edition**

The previous edition (First) was published January 31, 2024. The following updates are included in this Second edition.

#### Laws

# Removed Title 3 – Agriculture & Forestry

Act 752 of the 2024 Regular Session made significant changes to the consumable hemp product law, with the intended goal of reducing the amount of THC available in such products to an amount less than what is available in medical marijuana products in the state. A pharmacy, like any other retail business, may apply for a retail permit to sell consumable hemp products from the state office of alcohol and tobacco control. The decision to sell such products is a business decision with no significant impact on pharmacy practice. We have removed this title.

#### Added Title 14 - Criminal Law

Act 548 of the 2022 Regular Session created the crime of criminal abortion by means of abortion-inducing drugs. The legislation also created a safe harbor for the lawful use of an abortion-inducing drug for a bona fide medical reason, and further, noted the requirements for both prescriber and dispenser for such prescriptions.

### Added Title 17 – Education

Act 378 of the 2024 Regular Session amended the state education law, more specifically the section permitting elementary and secondary schools to administer medications. In particular, the law permits prescribers authorized to prescribe life-saving medications to issue prescriptions for those drugs in the name of a school, authorizes pharmacists to dispense such medications pursuant to those prescriptions, and authorizes schools to administer such medications. Since the prescription is to be issued in the name of a school, we have added this law to inform readers of that exception to the notion that prescriptions are usually issued to specifically-named patients.

### Amended Title 37 – Professions & Occupations

- Act 711 of the 2024 Regular Session amended the pharmacy practice law in Chapter 14 by adding a new section authorizing pharmacists to perform a rapid HIV test or order laboratory testing for HIV infection for any person 17 years of age or older; and further, to dispense up to a 30-day supply of HIV pre-exposure prophylaxis and up to a 28-day supply of HIV post-exposure prophylaxis in the absence of any prescription drug order. The state health department is required to promulgate rules to implement this new law no later than March 2025.
- Act 644 of the 2024 Regular Session amended the pharmacy practice law in Chapter 14 by making a change to one of the reasons for which the board may discipline a license. In particular, the term 'moral turpitude' was removed.
- Removed Chapter 59, relative to licensure procedures for individuals with military training, consistent with this book's focus on laws relative to pharmacy practice.

# Amended Title 40 – Public Health & Safety

- ➤ Edited Part I of Chapter 4, the state food, drug, and cosmetic law, to exclude certain sections relative to food and cosmetics, retaining sections relative to drugs and administrative procedures.
- ➤ Act 110 of the 2024 Regular Session amended the state list of controlled substances by adding 13 substances to Schedule I as well as Zuranolone to Schedule IV.
- Acts 143 and 732 of the 2024 Regular Session added Tianeptine to Schedule I of the state list of controlled substances.
- Act 246 of the 2024 Regular Session added Mifepristone and Misoprostol to Schedule IV of the state list of controlled substances. In addition, the legislation established the crime of coerced criminal abortion with use of an abortion-inducing drug. The legislature directed the board of pharmacy to notify all pharmacists of this law, and further, that lawful prescriptions for Mifepristone and Misoprostol may be dispensed in accordance with R.S. 14:87.9(C)(6). The board issued that notice via its Bulletin No. 24-01 as well as its July 2024 newsletter. As noted above, we have added that law in Title 14 to this publication.
- Edited Part X of Chapter 4, the controlled substance law, to remove several sections relative to criminal penalties for violations of the controlled substance law as well as several sections relative to judicial procedures for such violations.
- ➤ Act 205 of the 2024 Regular Session amended the controlled substance law, to permit the transfer between pharmacies of a prescription or prescription information for controlled substances in conformance with the federal rules for that activity.
- ➤ Act 248 of the 2024 Regular Session amended the controlled substance law by prohibiting the retail sale of nitrous oxide. The legislation provided exemptions for legitimate medical and industrial applications.
- Removed Part X-B, the drug paraphernalia law.
- Removed Part X-D, the civil forfeiture law relative to controlled substance cases.
- Acts 150 and 693 of the 2024 Regular Session made significant revisions to the medical marijuana law. Among other changes, the legislation transferred the regulatory authority for medical marijuana from the board of pharmacy to the state health department. Effective January 2025, marijuana pharmacies will no longer hold a license from the board but will hold a marijuana retail permit from the state health department. We have removed that Part X-E relative to medical marijuana.
- Act 657 of the 2024 Regular Session created a new section in Chapter 5-C of the public health law permitting a broad range of entities to stock life-saving medications. This law is similar to the new law noted above in Title 17. That law was for elementary and secondary schools; this law includes a number of other entities and specifically excludes elementary and secondary schools. In particular, the law permits prescribers authorized to prescribe life-saving medications to issue prescriptions for those drugs in the name of the entity, authorizes pharmacists to dispense such medications pursuant to those prescriptions, and authorizes entities to administer such medications. Since the prescription is to be issued in the name of an entity, we have added this law to inform readers of that exception to the notion that prescriptions are usually issued to specifically-named patients.
- Act 750 of the 2024 Regular Session created a new section of public health law permitting the use of individualized investigational drugs, biological products and devices.
- Act 624 of the 2024 Regular Session amended the recently-enacted healthcare workplace violence prevention law to clarify the requirements of that law are not applicable to regulated entities when it employs five or fewer licensed medical providers, e.g., pharmacists.

### Rules

### Amended Chapter 1 – Introduction

➤ Section 105 was amended in August 2024 to provide for participation in open meetings via electronic means for people with disabilities, as required by <u>Act 393</u> of the 2023 Regular Session of the Louisiana Legislature.

#### Amended Chapter 5 – Pharmacists

➤ Section 501 was amended in March 2024 to remove the requirement for an application for a pharmacist license to be submitted to the board office at least 30 days prior to taking any licensure examination.

# Amended Chapter 11 – Pharmacies

➤ Section 1103 was amended in August 2024 to require prescription departments to be maintained in a clean and orderly condition, and further, to require all areas where drugs are stored to be maintained under environmental conditions which will ensure the integrity of the drug, as specified by USP or the manufacturer's or distributor's product information or labeling.

# Amended Chapter 25 – Prescriptions, Drugs, and Devices

➤ Section 2501 was amended in August 2024 to require all areas where drugs are stored to be maintained under environmental conditions which will ensure the integrity of the drug, as specified by USP or the manufacturer's or distributor's product information or labeling.

# Amended Chapter 29 – Prescription Monitoring Program

- ➤ Section 2901 was amended in March 2024 to update the definition of "Drug of Concern", to include all butalbital products except those listed in any schedule of controlled substances and to remove naloxone from that definition.
- Section 2905 was added in August 2024 to provide for open meetings of the PMP Advisory Council via electronic means as well as participation in such electronic meetings by people with disabilities, as required by <a href="Act 14">Act 14</a> of the 2023 Regular Session of the Louisiana Legislature.
- ➤ Section 2914 was amended in March 2024 to provide a record retention schedule for prescription monitoring program information. The board shall maintain at least 5 years of transaction data for direct review, shall archive data not available for direct review up to 10 years, and may destroy any data after 10 years. The archival and destruction of PMP data was authorized by <a href="Act 189">Act 189</a> of the 2016 Regular Session of the Louisiana Legislature.

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# Louisiana Revised Statutes

#### Title 14 – Criminal Law

# Chapter 1 – Criminal Code

# Part V. Offenses Affecting the Public Morals

# **Subpart H. Offenses Affecting Sexual Immorality**

\* \* \*

No. 3. Abortion

\* \* \*

#### §87.9. Criminal abortion by means of abortion-inducing drugs

- A. Criminal abortion by means of an abortion-inducing drug is committed when a person knowingly causes an abortion to occur by means of delivering, dispensing, distributing, or providing a pregnant woman with an abortion-inducing drug.
- B. (1) Any person who knowingly performs an abortion by means of an abortion-inducing drug in violation of this Section shall be imprisoned at hard labor for not less than one nor more than five years, fined not less than five thousand nor more than fifty thousand dollars, or both.
  - (2) Any person who knowingly performs an abortion by means of an abortion-inducing drug in violation of this Section that results in the death or serious bodily injury of the pregnant woman shall be imprisoned at hard labor for not less than five nor more than ten years, fined not less than ten thousand nor more than seventy-five thousand dollars, or both.
  - (3) Any person who knowingly performs or induces an abortion that results in the death or serious bodily injury of a pregnant woman under the age of eighteen in violation of this Section shall be imprisoned at hard labor for not less than fifteen nor more than fifty years, fined not less than fifteen thousand nor more than one hundred thousand dollars, or both.
- C. None of the following shall be construed to create the crime of criminal abortion by means of an abortion-inducing drug:
  - (1) Any action taken when a physician or other licensed medical professional is acting in the course of administering lawful medical care.
  - (2) Any act taken or omission by a pregnant woman with regard to her own unborn child.
  - (3) Possessing for her own consumption or consuming an abortion-inducing drug by a pregnant woman in violation of this Section.
  - (4) Lawfully prescribing, dispensing, or distributing a drug, medicine, or other substance for a bona fide medical reason that is not intended to cause an abortion in violation of this Section.
  - (5) (a) The act of administering an abortion-inducing drug when the drug is administered by a physician licensed by the state of Louisiana who administers the abortion-inducing drug in person to the pregnant woman.
    - (b) The provisions of Subparagraph (a) of this Paragraph shall not be a defense against prosecution under any other provision of law that makes the abortion unlawful, whether the other provision of law is in effect on August 1, 2022, or becomes unlawful at a later date.
  - (6) Any act by a licensed pharmacist or pharmacy related to filling a prescription for a drug, medicine, or other substance prescribed for a bona fide medical reason shall not subject the pharmacist or the pharmacy to the criminal consequences of this Section. A diagnosis or a diagnosis code shall be written on the prescription by the prescriber indicating that the drug, medicine, or other substance is intended for a purpose other than to cause an abortion in violation of this Section.

(Section added by Act 548 of the 2022 Regular Session)

[End of §87.9]

\* \* \*

[End of Title 14]

#### Title 17 – Education

# **Chapter 2 – Teachers and Employees**

#### **Part I. General Provisions**

\* \* \*

# §436.1. Administration of medication; definition; conditions; restrictions; exceptions \*

- O. (1) Notwithstanding any other provision of law to the contrary, licensed health professionals authorized to prescribe medication may prescribe life-saving medications that are maintained in the name of a school for use in accordance with Paragraph (3) of this Subsection, licensed pharmacists and physicians may dispense such medications, and a school may maintain a stock supply of such medications in accordance with a prescription issued pursuant to this Paragraph. The state Department of Education shall develop and distribute a list of such medications.
  - (2) As used in this Subsection:
    - (a) "Life-saving medication" means any medication that can be administered to treat any life-threatening condition.
    - (b) "Trained school personnel" means a school employee or volunteer who has received the training on life-saving medications that addresses techniques on how to recognize signs of a life-threatening emergency, standards and procedures for the storage and administration of the medication, and emergency follow-up procedures, including the requirement to summon emergency services either immediately before or immediately after administering the medication.
  - (3) The governing authority of a public or nonpublic school may authorize school nurses and other trained school personnel to administer life-saving medication to a student or other person on a school premises or during a school-affiliated activity when they believe in good faith to be experiencing a medical emergency in accordance with a standing protocol of licensed health professionals authorized to prescribe medication, regardless of whether the student or other person has a prescription for the medication. Training for the administration of such medication may be provided by a medical emergency training organization, a registered nurse, or a licensed physician.
  - (4) The governing authority may enter into arrangements with manufacturers or suppliers of such medications to obtain them at fair-market, free, or reduced prices.
  - (5) The following are not liable for damages in a civil action for injury, death, or loss to person or property that allegedly arises from a act or omission associated with administration or self-administration of a life-saving medication, unless the act or omission constitutes willful or wanton misconduct:
    - (a) A public or nonpublic school.
    - (b) A public or nonpublic school employee or volunteer.
    - (c) A licensed health professional authorized to prescribe medication who personally furnishes or prescribes a life-saving medication.
    - (d) A training organization and its personnel.
  - (6) The administration of life-saving medication as provided in this Section does not constitute the practice of medicine or nursing.

(Subsection O added by Act 378 of the 2024 Regular Session)

[End of §436.1.]

\* \* \*

[End of Title 17]

# **Title 37 – Professions and Occupations**

# Chapter 14 – Louisiana Pharmacy Practice Act

[The Louisiana Pharmacy Practice Act was substantially revised and reorganized by Act 767 of the 1999 Regular Session, effective August 15, 1999. It consisted of Parts I through V; subsequent amendments are noted herein.]

#### Part I. 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 <u>Administrative Procedure Act</u> 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 whose graduate has attained educational equivalency status through a mechanism established by the board.
- (3) (a) "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.
  - (b) A profile-driven system requires that medication orders or 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.
  - (c) (i) A non-profile-driven system does not require prior or concomitant pharmacist review of medication orders or 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 or first dose cabinet.
    - (ii) "Floor stock or 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 or 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) "Biological product" has the meaning assigned by Section 351 of the Public Health Service Act, 42 U.S.C. 262.
- (5) "Board" means the Louisiana Board of Pharmacy.
- (6) "Chart Order" is a lawful order entered on the electronic or paper chart or medical record of an inpatient or resident of an institutional facility by a practitioner or his licensed healthcare designee for a drug or device and shall be considered a prescription drug order provided it contains the following:

- (a) Full name of the patient.
- (b) Date of issuance.
- (c) Name, strength, and dosage form of the drug prescribed.
- (d) Directions for use.
- (e) Name of the prescribing practitioner.
- (f) The prescribing practitioner's written or electronic signature or the written or electronic signature of the practitioner's licensed healthcare designee, who shall be a licensed nurse, pharmacist, or physician practicing in a long-term care facility. The licensed healthcare designee shall be authorized to document a chart order in the patient's medical record on behalf of the prescribing practitioner pending the prescribing practitioner's signature, or to communicate a prescription to a pharmacy whether telephonically, by facsimile transmission, or electronically.
- (7) "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.
- (8) "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 healthcare 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.
- (9) "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.
- (10) "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.
- (11) "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", the label "Rx Only", or both, or any other designation required under federal law.
- (12) "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.
- (13) "Distribute" or "distribution" means the delivery of a drug or device other than by administering or dispensing.
- (14) "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 other animals
  - (b) any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.
  - (c) any substance other than food intended to affect the structure or any function of the body of humans or other animals.
- (15) "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.
    - (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.
  - (d) Review of the prescription drug order and patient record for proper utilization including over- or underutilization, and optimum therapeutic outcomes.
- (16) "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.
- (17) "Emergency drug kit" for long-term care facilities 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 needs of a

resident or patient.

- (18) "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:
    - (i) 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.
    - (ii) 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.
- (19) "Final checks of work" is the requirement that only a pharmacist supervises and releases the completed product prepared by a pharmacy technician.
- (20) "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.
- (21) "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.
- (22) "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.
- (23) "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.
- (24) "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.
- (25) "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 Louisiana Department of Health.
- (26) "Manufacturer" means a person who manufactures drugs and includes a labeler, primary distributor, or person who prepares drugs in dosage form by mixing.
- (27) "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.
- (28) "Medical order" means a lawful order of a practitioner that may or may not include a prescription.

- (29) "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.
- (30) "Off-site facility" means and refers to the location of a building that houses a licensee of the Louisiana Department of Health, but which does not house a board-permitted pharmacy.
- (31) "On-site facility" means and refers to the location of a building that houses a board-permitted pharmacy.
- (32) "Out-of-state pharmacy" means a pharmacy located outside this state.
- (33) "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.
- (34) "Permit" means the grant of authority by the board to any person authorizing the practice of pharmacy at a site.
- (35) "Person" means an individual, corporation, partnership, association, or any other legal entity, including government.
- (36) "Pharmacist" means an individual currently licensed by the board to engage in the practice of pharmacy in the state.
- (37) "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.
- (38) "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.
- (39) (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 <u>Administrative Procedure Act</u> by publishing their respective notices of intent no later than one hundred twenty days following August 15, 2006.
    - (ii) If both boards have not initiated the rulemaking process in accordance with the provisions of the <u>Administrative Procedure Act</u> by publishing their respective notices of intent by one hundred twenty days following August 15, 2006, 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 August 15, 2006.
    - (iii) If the boards have not initiated the rulemaking process in accordance with the provisions of the <u>Administrative Procedure Act</u> by publishing their respective notices of intent by one hundred eighty days following August 15, 2006, then the Louisiana Board of Pharmacy shall have the authority to promulgate the rule required in <u>R.S. 37:1164(39)</u> independently of the Louisiana State Board of Medical Examiners.
  - (c) A statewide advisory committee established by the Louisiana State Board of Medical Examiners in carrying out its duties relative to collaborative drug therapy management may conduct and its members may attend and participate in a meeting via electronic means in accordance with R.S. 42:17.3<sup>1</sup>.
- (40) "Pharmacy-generated drug" means a drug made by a pharmacy.
- (41) "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.
- (42) "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.
- (43) "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.

- (44) "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.
- (45) "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.
- (46) "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.
- (47) "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.
- (48) "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.
- (49) "Probation" means a restriction of pharmacy practice for a specified period of time.
- (50) "Reciprocity" means the acknowledgment and licensure of a pharmacist from another state or jurisdiction pursuant to procedures established by the board.
- (51) "Reprimand" means a formal reproof of a person for violation of this Chapter or rules and regulations of the board.
- (52) "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.
- (53) "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.
- (54) "Significant adverse drug reaction" means any drug-related incident that may result in serious harm, injury, or death to the patient.
- (55) "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.
- (56) "Suspension" means the withdrawal of the license, permit, certification, or registration to practice pharmacy in the state for a period of time.
- (57) "Warning" means a written notice issued to a person addressing possible aberrant conduct.
- (58) "Wholesale drug distribution" means distribution of legend drugs to a party other than the consumer or patient, including but not limited to distribution by manufacturers, repackers, own label distributors, jobbers, and wholesale drug distributors.
- (59) "Wholesale drug distributor" means any person who sells legend drugs to a party other than the consumer or the patient, including but not limited to manufacturers, repackers, own label distributors, jobbers, brokers, agents, and pharmacies.

(Section amended by Acts 164 and 627 of the 2006 Regular Session; Acts 112 and 168 of the 2013 Regular Session; Act 391 of the 2015 Regular Session; Acts 64, 206, and 602 of the 2018 Regular Session)

#### [End of Part I]

### Part II. Board of Pharmacy

# §1171. Louisiana Board of Pharmacy; creation

The Louisiana Board of Pharmacy is hereby created within the Louisiana Department of Health and is subject to the provisions of R.S. 36:803. The board shall carry out the purposes and enforce the provisions of this Chapter.

#### §1172. Membership

- A. The board shall consist of seventeen members appointed by the governor, including two licensed pharmacists from each of the pharmacy districts as provided in R.S. 37:1173 and one representative of the consumers of Louisiana from the state at-large, who possess the qualifications specified in R.S. 37:1174. The governor shall ensure that his appointments demonstrate race, gender, ethnic, and geographical diversity.
- B. Each appointment by the governor shall be subject to Senate confirmation. (Section amended by Act 515 of the 2018 Regular Session)

### §1173. Pharmacy districts

The pharmacy districts shall be comprised of the following parishes:

- (1) District One shall be comprised of the parishes of Jefferson and St. Tammany.
- (2) District Two shall be comprised of the parishes of Orleans, Plaquemines, and St. Bernard.
- (3) District Three shall be comprised of the parishes of Ascension, Assumption, Iberia, Iberville, Lafourche, St. Charles, St. James, St. John the Baptist, St. Martin, St. Mary, Terrebonne and West Baton Rouge.
- (4) District Four shall be comprised of the parishes of Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches, Red River, Sabine and Webster.
- (5) District Five shall be comprised of the parishes of Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, West Carroll, and Winn.
- (6) District Six shall be comprised of the parishes of East Baton Rouge, East Feliciana, Livingston, St. Helena, Tangipahoa, Washington, and West Feliciana.
- (7) District Seven shall be comprised of the parishes of Acadia, Calcasieu, Cameron, Jefferson Davis, Lafayette, and Vermilion.
- (8) District Eight shall be comprised of the parishes of Allen, Avoyelles, Beauregard, Catahoula, Concordia, Evangeline, Grant, LaSalle, Pointe Coupee, Rapides, St. Landry, and Vernon.

### §1174. Qualifications

- A. Each pharmacist member of the board shall at the time of appointment:
  - (1) Be a resident of this state for not less than six months.
  - (2) Be currently licensed to engage in the practice of pharmacy in this state.
  - (3) Be actively engaged in the practice of pharmacy in this state and may practice in and own a Louisianapermitted pharmacy.
  - (4) Have two years of experience in the practice of pharmacy in this state after licensure.
  - (5) Shall not have been convicted of a felony.
  - (6) Shall not have been placed on probation by the board.
- B. (1) The consumer member of the board shall possess all of the following qualifications:
  - (a) Is a citizen of the United States and has been a resident of Louisiana for at least one year immediately prior to the appointment.
  - (b) Has attained the age of majority.
  - (c) Has never been licensed by any of the licensing boards identified in R.S. 36:259(A), nor shall he have a spouse who has ever been licensed by a board identified in R.S. 36:259(A).
  - (d) Has never been convicted of a felony.
  - (e) Does not have and has never had a material financial interest in the healthcare profession.
  - (2) The consumer member shall be a full voting member of the board with all rights and privileges conferred on board members, except that the consumer member shall not participate in the grading of individual examinations.

(Section amended by Act 515 of the 2018 Regular Session; Act 52 of the 2019 Regular Session)

# §1175. Appointment process; vacancies

- A. The governor shall appoint the members of the board in accordance with other provisions of this Section and the state constitution.
- B. When a vacancy occurs in the membership of the board representing one of the eight districts for any reason, including expiration of term, removal, resignation, death, disability, or disqualification, the following nominating process shall be satisfied:
  - (1) The pharmacist making the nomination shall be a resident of the district where the vacancy occurs.
  - (2) The pharmacist nominee shall be a resident of the district where the vacancy occurs.
  - (3) Nomination ballots shall be returned to the board office at least sixty days prior to a vacancy occurring by an expiring term.
  - (4) Nomination ballots shall be returned to the board office at least thirty days following a vacancy occurring by death, resignation, inability to act, or other cause.
  - (5) The nominee shall not have been convicted of a felony.
  - (6) The nominee shall not have been placed on probation by the board.
- C. When the vacancy in question involves the consumer representative, the governor shall fill the vacancy at his pleasure without following the procedure set forth in Subsection B of this Section, provided the consumer representative meets the requirements for such member specified in this Section.
- D. The secretary of the board shall be charged with the duty of forwarding to each licensed pharmacist, by United States mail, to the last known address indicated in the board's records, a nomination ballot. The ballot, or an

accompanying communication, shall indicate the date, time, and place, for the counting of ballots. At a gathering open to the public, the ballots shall be counted openly by the secretary or by one or more individuals designated by the president. The secretary shall certify to the governor the names of the three nominees receiving the highest number of nominations. From the names submitted to him in this manner, the governor may select and appoint one eligible individual to fill the vacancy in question.

- E. In the absence of the secretary, or in the event of his inability or failure to act, the duties of the secretary with respect to the mailing and counting of ballots and the certification to the governor shall be performed by the president of the board.
- F. The successor to each member of the board appointed from a pharmacy district shall be appointed from the district having the same number designation as the district from which the member who is being replaced was appointed.
- G. Each member of the board appointed from a district to fill a vacancy occurring by death, resignation, inability to act, or other cause, shall serve for the remainder of the term of his predecessor.

### §1176. Removal

- A. A board member may be removed upon one or more of the following grounds:
  - (1) The refusal or inability for any reason to perform his duties as a member of the board in an efficient, responsible, and professional manner;
  - (2) The misuse of office to obtain personal, pecuniary, or material gain or advantage for himself or another through such office;
  - (3) The violation of the laws governing the practice of pharmacy or the distribution of drugs or devices.
- B. Removal of a member of the board shall be in accordance with the <u>Administrative Procedure Act</u> or other applicable laws.
- C. The governor may remove any member of the board for good cause.

(Section amended by Act 271 of the 2022 Regular Session)

#### §1177. Terms

- A. Except as provided in <u>Section 1175</u>, pharmacist members of the board shall be appointed for a term of six years, beginning on July 1 of the year in which the appointment is made.
- B. The terms of the pharmacist members of the board shall be staggered, so that the terms of no more than six pharmacist members shall expire in any year. Each member shall serve until a successor is appointed and qualified.
- C. The at-large consumer representative shall serve at the pleasure of the governor.

(Section amended by Act 233 of the 2012 Regular Session)

### §1178. Compensation of board members

- A. In accordance with the fee schedule provided in R.S. 37:1184<sup>2</sup>, members of the board shall receive a per diem.
- B. Notwithstanding the provisions of <u>R.S. 39:231</u>, the members of the board may be reimbursed for actual and reasonable expenses approved by the board in connection therewith while attending regular or called board meetings or attending to official business of the board.

(Section amended by Act 1052 of the 2003 Regular Session)

# §1179. Organization

- A. The board shall elect from its members a president, secretary, and one or more vice presidents. The president of the board shall preside at all meetings of the board and shall be responsible for the performance of all duties and functions of the board required or permitted by this Chapter. Each additional officer elected by the board shall perform those duties normally associated with his position and such other duties assigned to him by the board.
- B. Officers elected by the board shall serve terms commencing with the day of their election and ending upon election of their successors.
- C. Any officer may be removed from office by majority vote of the board, for proper cause after due notice and an opportunity to be heard.
- D. The president of the board or, in his absence, the highest-ranking vice president, shall preside at all meetings. The president of the board is the executive officer of the board.
- E. The president or the secretary of the board may administer oaths in connection with the duties of the board.
- F. The executive director shall be a licensed pharmacist under the provisions of this Chapter and shall not serve concurrently as a member of the board. The executive director shall be in charge of the daily operations of the office of the board. The executive director's responsibilities include, but are not limited to, the following:
  - (1) Shall furnish a bond in an amount to be fixed by the board, conditioned upon the faithful performance and discharge of the duties of his office according to law.

- (2) Shall receive a salary fixed by the board, and all necessary expenses incurred in the performance of his official duties.
- (3) Make disbursements by check, voucher, or any other reasonable means deemed appropriate by the board and as authorized by the president and the executive director.
- (4) Attend to the correspondence, and perform such other duties as the board may reasonably require.
- (5) Make, keep, and preserve all books, registers, and records, and be in charge of same, and deliver them to his successor in office.
- (6) If so authorized by the board, supervise and direct the activities of the board's inspectors and investigators, direct and supervise the clerical personnel appointed to assist the board, and undertake other duties as directed by the board with the aid of clerical personnel as necessary for the fulfillment of his duties and responsibilities.
- (7) Receive and receipt for all fees collected.

### §1180. Meetings

- A. The board shall meet at least once every twelve months to transact its business. The board shall meet as it deems appropriate. Such additional meetings may be called by the president of the board or by two-thirds of the members of the board.
- B. The board shall meet at such place determined prior to giving notice of such meeting and the place of the meeting shall not be changed after such notice is given without adequate prior notice.
- C. Notice of all meetings of the board shall be given in the manner and pursuant to requirements prescribed by the Administrative Procedure Act.
- D. A simple majority of the members of the board shall constitute a quorum for the conduct of a board meeting and, except where a greater number is required by this Chapter or by any rule to the board, all actions of the board shall be approved by a majority of a quorum.
- E. All board meetings and hearings shall be open to the public. The board may, in its discretion and according to law, conduct any portion of its meeting in executive session, closed to the public.

#### §1181. Domicile of board

The domicile of the board shall be Baton Rouge, Louisiana.

#### §1182. Powers and duties of the board

- A. The board shall be responsible for the control and regulation of the practice of pharmacy and shall:
  - (1) Make necessary rules and regulations to carry out the purposes and enforce the provisions of this Chapter and furnish copies of them upon request.
  - (2) Hold meetings at least once a year and at other times when necessary for the transaction of business that may legally come before it.
  - (3) Make a written report annually to the governor.
  - (4) Report to the attorney general of the state all persons violating the provisions of this Chapter.
  - (5) License by examination applicants who are qualified to engage in the practice of pharmacy under the provisions of this Chapter.
  - (6) License by reciprocity pursuant to the provisions of this Chapter.
  - (7) Administer examinations as deemed necessary.
  - (8) Issue and renew licenses, permits, certifications, registrations and any other designations deemed necessary to engage in the practice of pharmacy.
  - (9) Establish and enforce compliance with professional standards and rules of conduct of pharmacists engaged in the practice of pharmacy.
  - (10) Determine and issue standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this state, and the specification and enforcement of requirements for practical training, including internship.
  - (11) Enforce those provisions of this Chapter related to conduct and competence, including but not limited to revocation, summary suspension, suspension, probation, reprimand, warnings, or fines.
  - (12) Regulate, license, certify, and register the training, qualification, and employment of pharmacy interns and pharmacy technicians.
  - (13) Establish minimum specifications for the physical facilities, technical equipment, environment, supplies, personnel, and procedures for the storage, compounding, and dispensing of drugs or devices.
  - (14) Inspect in a lawful manner the legend drugs and devices which are sold, offered, or exposed for sale, or kept for sale, or which are compounded or dispensed, or kept for compounding or dispensing, at any site, and shall seize any legend drugs and devices found to constitute an imminent danger to the public health, safety,

- and welfare.
- (15) Inspect during hours of operation any licensed, permitted, certified, or registered person, including, but not limited to, pertinent records for the purpose of determining if any provisions of law governing the legal distribution of drugs or devices or the practice of pharmacy are being violated.
- (16) Cooperate with all agencies charged with the enforcement of the laws of the United States, of this state, and of all other states relating to drugs, devices, and the practice of pharmacy.
- (17) Except as otherwise provided to the contrary, exercise all of its duties, powers, and authority in accordance with the <u>Administrative Procedure Act</u>.
- (18) Make, keep, and preserve all books, registers, and records.
- (19) Receive and receipt all fees collected.
- (20) Make disbursements by check, voucher, or any other reasonable means deemed appropriate by the board and authorized by the president and the executive director.
- (21) In accordance with R.S. 37:1184<sup>2</sup>, establish by regulation fees and costs to be imposed for the purpose of implementing and enforcing the provisions of this Chapter.
- (22) Have the authority to request and obtain state and national criminal history record information on any person applying for any license, registration, certificate, permit, or any other designation deemed necessary to engage or assist in the practice of pharmacy which the board is authorized by law to issue.
- (23) Have the authority to require of any applicant for any license, registration, certificate, permit, or any other designation deemed necessary to engage or assist in the practice of pharmacy which the board is authorized by law to issue, to provide information which may be necessary to verify an applicant's identity including birth certificates, passport documents, legal status documents, and any other biometric information deemed appropriate by the board. The board may charge and collect from an applicant all fees and costs related thereto.
- (24) Have the authority to compel any person applying for or holding any license, registration, certificate, permit, or any other designation deemed necessary to engage or assist in the practice of pharmacy to submit to an evaluation by such persons as the board may designate.

#### B. The board may:

- (1) Join such professional organizations and associations organized exclusively to promote the improvement of the standards of the practice of pharmacy for the protection of the health, safety, and welfare of the public or whose activities assist and facilitate the work of the board.
- (2) Receive and expend funds, in addition to its annual or biennial appropriation, from parties other than the state, provided that the following conditions are met:
  - (a) Such funds are awarded for the pursuit of a specific objective which the board is authorized to accomplish by this Chapter, or which the board is qualified to accomplish by reason of its jurisdiction or professional expertise.
  - (b) Such funds are expended for the pursuit of the objective for which they are awarded.
  - (c) Activities connected with or occasioned by the expenditures of such funds do not interfere with the performance of the board's duties and responsibilities, and do not conflict with the exercise of the board's powers as specified by this Chapter.
  - (d) Such funds are kept in a separate, special account.
  - (e) Periodic reports are made concerning the board's receipt and expenditure of such funds.
- (3) Conduct any investigation, inquiry, or hearing which the board is authorized to hold as required by this Chapter.
- (4) Place under seal all drugs or devices that are owned by or in the possession, custody, or control of a licensee at the time his license is suspended or revoked or at the time the board refuses to renew his license. Except as otherwise provided in this Section, drugs or devices so sealed shall not be disposed of until appeal rights under the <u>Administrative Procedure Act</u> have expired, or an appeal filed pursuant to that Act has been determined.
- (5) Collect professional demographic data.
- (6) Employ or contract for inspectors, chemists, agents, clerical help, legal assistance, and other personnel necessary for the proper operation of the board office and for any other purpose under this Chapter.
- (7) Establish minimum standards for maintaining the integrity and confidentiality of prescription information and other patient health care information.
- (8) Acquire, develop, maintain, expand, sell, lease, mortgage, borrow funds, or otherwise contract with respect to immovable property as it may deem necessary or appropriate to accomplish the provisions of this Chapter. The board shall have the authority to borrow funds with the approval of the State Bond Commission and to expend funds of the board for the acquisition of immovable property and improvements thereon. In the event that the board sells immovable property and improvements thereon, the revenue derived from the sale shall be retained by the board and shall not be subject to reversion to the state general

fund

(9) Assess and collect expenses incurred for the inspection of nonresident licensees. (Section amended by Act 1052 of the 2003 Regular Session; Act 131 of the 2004 Regular Session; Act 282 of the 2013 Regular Session; Act 206 of the 2018 Regular Session)

# §1183. Records prima facie evidence

The books, registers, and all records of the board shall be prima facie evidence of the matter therein recorded, in any court of law.

# §1184. Fees

Notwithstanding any other provision of this Chapter, the fees and costs established by the board in accordance with R.S. 37:1182(A) shall not be less than the following schedule:

<u>K.5</u>	. 37.1	102(A) shall not be less than the following schedule.	Minimum
(1)	Mis	cellaneous fees and costs	
	(a)	Photocopies of documents per page	\$0.50
	(b)	Certification of document as true copy	\$5.00
	(c)	Certification of document as office record	\$5.00
	(d)	Certification of license	\$20.00
	(e)	Official list of licensed pharmacists	\$150.00
	(f)	Official list of certified technicians	\$150.00
	(g)	Official list of pharmacy permits	\$150.00
	(h)	Handling and mailing per page	\$1.00
	(i)	Administrative hearing fee	\$250.00
	(j)	Pharmacy intern registration	\$10.00
	(k)	Law book	\$40.00
	(1)	Certification of practical experience to another state	\$10.00
	(m)	Official list of registered pharmacy interns	\$150.00
(2)	(n)	Official list of registered pharmacy technician candidates	\$150.00
(2)		nses, permits, certification, registrations and examinations for pharmacists	ф100 00
	(a)	(i) Renewal fee for license, per year	\$100.00
	(l <sub>2</sub> )	(ii) Pharmacy education support fee, per year	\$100.00
	(b)	Delinquent fee in addition to renewal fee, per year	\$50.00
	(c)	Reinstatement of a license which has been suspended, revoked, or which has lapsed due to non-renewal	\$200.00
	(d)	Credential certification	\$50.00
	(u) (e)	Examination and licensing	\$300.00
	(f)	Reciprocity fees	\$150.00
	(g)	Certificates, duplicates	\$75.00
	(b)	Certificates, silver	\$100.00
	(i)	New issuance of certificates	\$75.00
(3)		nses, permits, certification, registration, and any other designations for pharmacy locations	
(-)	(a)	(i) New pharmacy permit fee	\$150.00
	(4)	(ii) Pharmacy education support fee, per year	\$100.00
	(b)	Pharmacy change of location	\$150.00
	(c)	Pharmacy change of ownership	\$150.00
	(d)	Pharmacy permit renewal fee, per year	\$125.00
	(e)	Delinquent permit renewal fee, per year	\$62.50
	(f)	Pharmacy CDS permit fee, per year	\$25.00
	(g)	Delinquent pharmacy CDS permit fee, per year	\$12.50
	(h)	Reinstatement of a permit which has been suspended, revoked, or which has lapsed due to	
		non-renewal	\$200.00
	(i)	Automated medication system registration, per year	\$150.00
	(j)	Emergency drug kits for long-term care facilities, per year	\$25.00
(4)	Cert	tification and examination for pharmacy technicians	
	(a)	Examination and certification	\$100.00
	(b)	Renewal certification fee, per year	\$50.00
	(c)	Certificate, duplicate	\$50.00
	(d)	Reinstatement of a pharmacy technician certificate which has been suspended, revoked,	
		or which has lapsed by non-renewal	\$200.00

	(e) Delinquent certificate renewal fee, per year		\$25.00	
	(f) Pharmacy technician candidate registration		\$25.00	
(5)	(5) Per diem		\$75.00	
(6)	(6) Permits for pharmacy benefit managers			
	(a)	Application fee for initial permit	\$500.00	
	(b)	Permit renewal fee, per year	\$500.00	
	(c)	Delinquent permit renewal fee, per year	\$250.00	
	2.5			

(Act 267 of the 2005 Regular Session amended Items (1)(g) and (k), (2)(a), (b) and (g), (3)(d), (e), (h) and (j), and (4)(c), and further, added Items(1)(l), (m) and (n) and (4)(e) and (f). Act 298 of the 2015 Regular Session added Items (2)(a)(ii) and (3)(a)(ii). Act 202 of the 2020 Regular Session added Items 6(a) through (c).

#### [End of Part II]

#### Part III. Licensing, Registration, and Certification of Persons

# §1201. Unlawful practice

- A. Except as otherwise provided in this Chapter, it shall be unlawful for any individual to engage in the practice of pharmacy unless currently licensed or registered to practice under the provisions of this Chapter.
- B. Licensed practitioners authorized under the laws of this state to compound drugs and to dispense drugs to their patients in the practice of their respective professions shall meet the same standards, record keeping requirements, and all other requirements for the dispensing of drugs applicable to pharmacists.
- C. It shall be unlawful for any individual to assist in the practice of pharmacy unless currently registered or certified by the board.

# §1202. Qualifications for licensure by examination

- A. To obtain a license to engage in the practice of pharmacy, an applicant for licensure by examination shall:
  - (1) Be at least twenty-one years of age.
  - (2) Be of good moral character and temperate habits.
  - (3) Meet one of the following educational requirements:
    - (a) Have graduated and received a professional degree from an approved college of pharmacy.
    - (b) Have graduated from a foreign college of pharmacy, completed a transcript verification program, taken and passed a college of pharmacy equivalency examination program, and completed a process of communication ability testing as defined by the board in order to assure that the applicant meets the standards necessary to protect public health, safety, and welfare.
  - (4) Have completed a minimum of one year of professional experience through an internship or other program that has been approved by the board under the supervision of a licensed pharmacist, which service shall be predominantly related to the provision of pharmacy primary care and the dispensing of drugs and medical supplies, the compounding of prescriptions, and the keeping of records and the making of reports as required under state and federal law.
  - (5) Have passed all examinations required by the board.
  - (6) Have paid fees specified by the board for the issuance of the license.
  - (7) Have submitted to the board a completed application form supplied by the board.
  - (8) Have completed a criminal history record check as authorized by R.S. 37:1216.

#### B. Examinations.

- (1) Due notice of all meetings for examination of applicants shall be given to all approved colleges of pharmacy in the state.
- (2) The board shall determine the content and subject matter of each examination and approve the site and date of the administration of the examination.
- (3) The examination shall be prepared to measure the knowledge of the applicant to engage in the practice of pharmacy. The board may employ, cooperate, and contract with any organization or consultant in the preparation and grading of an examination, but shall retain the sole discretion and responsibility for determining which applicants have passed such an examination.
- (4) Examination scores shall expire one year after the date of the examination. Expired scores shall not be valid for licensure.
- (5) An applicant, who takes any board required examinations and is unsuccessful, may repeat the examinations as administratively defined.
- (6) (a) An applicant who takes any board required examinations or any examination or examinations in other jurisdictions and is unsuccessful for the third time shall not thereafter be eligible to take the board

- examination without satisfying the requirements of the board as administratively defined.
- (b) An individual who has taken and failed the examinations more than three times may not practice as a pharmacy intern, as administratively defined.
- (c) An individual who has taken and failed for the third time a comparable examination to the board's examination within another jurisdiction shall not be eligible to take the examination of the board without satisfying the requirements of the board as administratively defined.
- C. Internship and other training programs.
  - (1) All applicants for licensure by examination shall obtain professional experience in the practice of pharmacy concurrent with attending or after graduation from an approved college of pharmacy, or both, under such terms and conditions as determined by regulation.
  - (2) The board shall establish such licensure requirements for pharmacy interns and standards for internship, or any other experiential program necessary to qualify an applicant for the licensure examination, and shall also determine the qualifications of pharmacists or other practitioners used in professional experience programs as determined by regulation.
- D. Issuance of License. Upon successful completion of the requirements of Subsections A, B, and C of this Section, the board shall issue a license to the pharmacist within fourteen working days.

(Section amended by Act 357 of the 2012 Regular Session; Act 31 of the 2018 Regular Session)

# §1203. Qualifications for reciprocity

- A. In order for a pharmacist currently licensed in another jurisdiction to obtain a license as a pharmacist by reciprocity in this state, an applicant shall:
  - (1) Have attained the age of twenty-one years.
  - (2) Have good moral character and be of temperate habits.
  - (3) Have possessed at the time of initial licensure as a pharmacist all qualifications necessary to have been eligible for licensure at that time in this state.
  - (4) Have presented to the board evidence of initial licensure by examination and evidence that such license is in active status.
  - (5) Have presented to the board evidence of any disciplinary, criminal, or other adverse action, including arrests taken against him by another licensing jurisdiction, government agency, law enforcement agency, or court. Such action may serve as grounds for the denial of reciprocity to an applicant.
  - (6) Have passed all examinations required by the board.
  - (7) Have paid the fees specified by the board to defray the expenses of making an investigation of the status of his original and all subsequently acquired pharmacist licenses.
  - (8) Have submitted a completed application form supplied by the board
- B. No applicant shall be eligible for licensure by reciprocity unless the state or jurisdiction in which the applicant was initially licensed as a pharmacist also grants reciprocity to a pharmacist duly licensed by examination in this state.
- C. Upon successful completion of the requirements of Subsections A and B of this Section, the board shall license the pharmacist within fourteen working days.

(Section amended by Act 164 of the 2006 Regular Session; Act 357 of the 2012 Regular Session; Act 31 of the 2018 Regular Session; Act 666 of the 2022 Regular Session)

#### §1204. Certificates to be signed by board

The board members shall sign all original pharmacist certificates of licensure issued by the board.

#### §1205. Duplicate certificates

In case a certificate of a licensed pharmacist is lost, destroyed, or otherwise missing, the board shall issue a duplicate thereof, upon receipt of an affidavit attested to by the pharmacist setting forth the facts and circumstances surrounding the loss of the certificate and payment of the fee or fees as specified by the board.

#### §1206. Silver certificate

The board may issue a silver certificate for twenty-five continuous years of registration.

#### §1207. Renewal of license, registration, and certification; expiration; reinstatement

A. (1) Each person licensed, registered, or certified by the board shall apply for renewal at a time designated by the board and pay a fee specified by the board. A person who desires to continue in the practice of pharmacy or assist in the practice of pharmacy in this state shall file with the board an application in such form and containing such data as the board may require, and complete such other requirements as deemed necessary by the board, for renewal.

- (2) (a) (i) The board shall assess on each pharmacist license renewal as required by this Section an additional fee of one hundred dollars per year to be designated as the "pharmacy education support fee." This fee shall be dedicated and allocated as specified in this Paragraph to an accredited school of pharmacy of a public university in this state. The board shall include on each license renewal form issued to a pharmacist an optional election whereby the person may elect not to remit the one hundred dollar pharmacy education support fee.
  - (ii) For purposes of this Paragraph, "accredited" shall mean possession of current accreditation from the Accreditation Council for Pharmacy Education.
  - (b) The board shall disburse all monies collected pursuant to this Paragraph to an accredited public university pharmacy school in this state on or before April first annually. The public university pharmacy school shall utilize these monies solely for the benefit of its pharmacy education program and the expenditure of such funds shall be approved by the board of supervisors of the university system of which the university is a member. The funds collected pursuant to this Paragraph shall be in addition to any other monies received by the university that operates the pharmacy school and are intended to supplement and not replace, displace, or supplant any other funds that the university receives from the state or from any other source.
- B. The board shall make available applications for renewal of licenses, registrations, and certificates to each licensed, registered, and certified person by a date designated by the board.
- C. If a person fails to make application to the board for renewal of his license, certification, or registration within a period determined by the board, the license, certification, or registration is expired and shall be deemed null and void.
- D. In order to reinstate the expired license, certification, or registration, the person shall meet requirements set by the board by regulation.

(Section amended by Act 357 of the 2012 Regular Session; Act 298 of the 2015 Regular Session; Act 202 of the 2020 Regular Session)

# §1208. Waiver of licensure or certification renewal while in military service

Upon written request of any licensed pharmacist or certified technician serving in active duty in the military service of the United States or any of its allies, the board may waive the requirement for the renewal of pharmacist license or technician certificate, including the renewal fees.

(Section amended by Act 358 of the 2012 Regular Session; Act 2020 of the 2020 Regular Session)

# §1208.1. Waiver of license or certification renewal fee for military spouse

Upon written request of any licensed pharmacist or certified technician who is the spouse of an active-duty member of the armed forces of the United States, the board may waive the requirement of the fee for the renewal of a pharmacist license or technician certificate in accordance with the rules promulgated by the board (Section added by Act 63 of the 2018 Regular Session)

#### §1209. Waiver of renewal fee when licensed fifty years; award

The board, in recognition of contributions to the practice of pharmacy, shall waive the renewal fee requirement for renewal of licensure for licensed pharmacists who have been duly registered and licensed to practice in Louisiana for not less than fifty years; in lieu thereof the board shall award to such pharmacists an honorary gold-embossed certificate. Such pharmacists desiring to continue to practice pharmacy shall file the renewal application and shall meet all other requirements for active licensure.

(Section amended by Act 164 of the 2006 Regular Session; Act 202 of the 2020 Regular Session)

#### §1210. Continuing education in pharmacy

The board shall establish requirements for continuing education in pharmacy, including the determination of acceptable program content. The board shall adopt rules and regulations necessary to carry out the stated objectives and purposes, to enforce the provisions of this Section.

# §1211. Pharmacy intern

The board shall establish an internship program for the purpose of providing the practical experience necessary for licensure as a pharmacist. The board shall adopt rules and regulations regarding the standards and qualifications for internship programs.

#### §1212. Pharmacy technicians

The board may register individuals as pharmacy technician candidates and certify individuals as pharmacy technicians,

both of whom may assist a pharmacist in the practice of pharmacy, as specified in board rules. Notwithstanding any provision in law to the contrary, in all cases, a pharmacist must verify the accuracy of a prescription before the drug or device may be transferred to a patient or patient's agent. The board may also set minimum training and education requirements and examinations for certification as a pharmacy technician as it deems necessary. The board may, by rule, establish ratios for pharmacy technician candidates to pharmacists and pharmacy technicians to pharmacists, but in no case shall such ratio be less than two pharmacy technicians to one pharmacist.

(Section amended by Act 131 of the 2004 Regular Session; Act 387 of the 2005 Regular Session)

### §1213. Notification of change of business place or employment

A pharmacist, pharmacy technician, pharmacy intern, or pharmacy technician candidate shall notify the board, in writing, of any change of employment within a time frame determined by the board by rule. (Section amended by Act 357 of the 2012 Regular Session)

## §1214. Notification of change of address

A pharmacist, pharmacy technician, pharmacy intern, or pharmacy technician candidate shall notify the board, in writing, of a change of address within a time frame determined by the board by rule. (Section amended by Act 357 of the 2012 Regular Session)

#### §1216. Authorization to obtain criminal history record information

- A. As used in this Section, the following terms shall have the following meaning:
  - (1) "Applicant" means an individual who has made application to the board for the issuance, or reinstatement of any license, registration, certificate, permit, or any other designation deemed necessary to engage or assist in the practice of pharmacy that the board is authorized by law to issue.
  - (2) "Bureau" means the Louisiana Bureau of Criminal Identification and Information of the office of state police within the Department of Public Safety and Corrections.
  - (3) "Criminal history record information" means information collected by state and federal criminal justice agencies on individuals consisting of identifiable descriptions and notations of arrests, detentions, indictments, bills of information, or any formal criminal charges, and any disposition arising therefrom, including sentencing, criminal correctional supervision, and release, but does not include intelligence for investigatory purposes, nor does it include any identification information which does not indicate involvement of the individual in the criminal justice system.
  - (4) "FBI" means the Federal Bureau of Investigation of the United States Department of Justice.
  - (5) "Licensure" means any license, permit, certification, or registration that the board is authorized to issue.
- B. In addition to any other requirements established by regulation, the board may require an applicant, as a condition for eligibility for licensure:
  - (1) To submit a full set of fingerprints, in a form and manner prescribed by the board.
  - (2) To permit the board to request and obtain state and national criminal history record information on the applicant.
  - (3) To collect from the applicant, in addition to all other applicable fees and costs, such amount as may be incurred by the board in requesting and obtaining state and national criminal history record information on the applicant.
- C. In accordance with the provisions and procedures prescribed by this Section, the board may request and obtain state and national criminal history record information from the bureau and the FBI relative to any applicant for licensure whose fingerprints the board has obtained pursuant to this Section for the purpose of determining the applicant's suitability and eligibility for licensure.
- D. Upon request by the board and upon the board's submission of an applicant's fingerprints, and such other identifying information as may be required, the bureau shall conduct a search of its criminal history record information relative to the applicant and report the results of its search to the board within sixty days from receipt of any such request. The bureau may charge the board a processing fee pursuant to <a href="R.S. 15:587">R.S. 15:587</a> for conducting and reporting on any such search.
- E. If the criminal history record information reported by the bureau to the board does not provide grounds for disqualification of the applicant for licensure under the applicable law administered by the board, the board shall have the authority to forward the applicant's fingerprints and such other identifying information as may be required to the FBI with a request for a search of national criminal history record information relative to the applicant.
- F. Any and all state or national criminal history record information obtained by the board from the bureau or FBI which is not already a matter of public record shall be deemed nonpublic and confidential information restricted to the exclusive use of the board, its members, officers, investigators, agents, and attorneys in evaluating the applicant's eligibility or disqualification for licensure. No such information or records related thereto shall, except

with the written consent of the applicant or by order of a court of competent jurisdiction, be released or otherwise disclosed by the board to any other person or agency.

(Section added by Act 1052 of the 2003 Regular Session)

## §1217. Authorization to compel evaluation

- As used in this Section the following terms shall have the following meaning:
  - (1) "Evaluation" means a diagnostic assessment for impairment by a board-approved addictionist.
  - (2) "Impaired" or "impairment" means a condition that causes an infringement on the ability of a person to practice, or assist in the practice, of pharmacy sufficient to pose a danger to the public. Impairment may be caused by but is not limited to alcoholism, substance abuse or addiction, mental illness, or physical illness.
  - (3) "Licensee" means an applicant for or a person renewing any license, registration, certificate, permit, or any other designation deemed necessary to engage in or assist in the practice of pharmacy issued by the board.
- B. In determining whether or not an impairment exists, the board, either through its impairment committee or upon joint agreement by the impairment committee chairman and the executive director, upon reasonable suspicion of such impairment shall have the authority to compel a licensee to submit to an evaluation, by such persons as the board may designate either in the course of an investigation or a disciplinary proceeding.
- C. Reasonable suspicion of impairment shall be presumed based upon preliminary evidence that the licensee is impaired based on specific objective and articulable facts and reasonable inferences drawn from those facts in light of experience. For purposes of this Section, facts and inferences may be based upon but not limited to any of the following:
  - (1) Observable phenomena while practicing or assisting in the practice of pharmacy such as direct observation of alcohol or drug use or abuse or of the physical symptoms or manifestations of being impaired due to alcohol or other drug use;
  - (2) Abnormal conduct or erratic behavior while at work or a significant deterioration in work performance;
  - (3) A report of alcohol or other drug use provided by a reliable and credible source;
  - (4) Evidence that a licensee has received a positive result from any drug or alcohol test during the individual's employment with an employer;
  - (5) Evidence that a licensee has tampered with any drug or alcohol test during the individual's employment with an employer; or
  - (6) Evidence that a licensee has illegally manufactured, sold, distributed, solicited, possessed, used, or transferred drugs.
- D. Information submitted pursuant to this Section shall be confidential and not subject to discovery by or release to any person or entity. The licensee shall submit to the board a release of information authorizing the board to obtain a report of such evaluation.
- E. A licensee shall be offered, at reasonable intervals, an opportunity to demonstrate that such person can resume the competent practice or assistance in the practice of pharmacy with reasonable skill and safety to patients.
- F. For the purpose of this Section, a licensee shall be deemed to have consented to submit to an evaluation when directed in writing by the board and further to have waived all objections to the admissibility of the testimony of the person conducting any evaluation at any proceeding or hearing before the board on grounds that such testimony or evaluation constitutes a privileged communication.
- G. In any proceeding by the board pursuant to the provisions of this Section, the record of such board proceedings involving the evaluation shall not be used in any other administrative or judicial proceeding outside of the board's jurisdiction
- H. Whenever the board directs a licensee to submit to an evaluation, the time from the date of the board's directive until the submission to the board of the report of the evaluation shall not be included in the computation of the time limit for any hearing that may occur in the matter.

(Section added by Act 1052 of the 2003 Regular Session)

#### §1218. Administration of influenza immunization

A pharmacist may administer an influenza immunization to any person seven years of age or older without a prescription or medical order, contingent upon all of the following provisions:

- (1) The pharmacist shall administer influenza immunizations in conformance with the most current annual influenza vaccination administration protocol as set forth by the United States Centers for Disease Control and Prevention Advisory Committee on Immunization Practice.
- (2) The pharmacist shall report each influenza immunization to the Louisiana Office of Public Health <u>Immunization</u> Registry at the time of the immunization or as soon as reasonably practicable thereafter.
- (3) The pharmacist shall report all adverse events he observes or which are reported to him to the <u>Vaccine Adverse</u> <u>Event Reporting System</u>, the cooperative program of the United States Centers for Disease Control and Prevention and the United States Food and Drug Administration for vaccine safety, or its successor program; and

- further, the pharmacist shall refer the patient with an adverse event to the influenza immunization for appropriate medical care.
- (4) The pharmacist shall maintain for at least two years a record of each influenza immunization administered.
- (5) The pharmacist shall obtain the appropriate credential to administer influenza immunizations from the board, as administratively defined, prior to administering any such immunization.

(Section added by Act 287 of the 2010 Regular Session; amended by Act 271 of the 2022 Regular Session)

## §1218.1. Administration of immunizations and vaccines other than influenza immunizations

- A. (1) A pharmacist may administer to an individual age seventeen or older an immunization or a vaccine without a patient-specific prescription or medical order if the immunization or the vaccine is administered in conformance with the most current immunization administration protocol as set forth by the United States Centers for Disease Control and Prevention Advisory Committee on Immunization Practice. At the time that a pharmacist administers an immunization or vaccine in accordance with the provisions of this Section, the pharmacist shall also inform the individual that the administration of an immunization or vaccine in accordance with the provisions of this Section is not to be construed as being in lieu of an annual checkup with the individual's primary care or family physician.
  - (2) The pharmacist shall report each immunization to the Louisiana Department of Health, office of public health's <u>Louisiana Immunization Network for Kids Statewide</u> at the time of the immunization or as soon as reasonably practicable thereafter, as this is the official state vaccination record.
  - (3) The pharmacist shall report all adverse events he observes or which are reported to him to the <u>Vaccine Adverse Event Reporting System</u>, the cooperative program of the United States Centers for Disease Control and Prevention and the United States Food and Drug Administration for vaccine safety, or its successor program; and further, the pharmacist shall refer the patient with an adverse event to an immunization for appropriate medical care.
  - (4) The pharmacist shall maintain for at least two years a record of each immunization administered.
  - (5) The pharmacist shall obtain the appropriate credentials to administer immunizations from the board, as administratively defined, prior to administering any such immunization.
  - (6) The pharmacist shall request the name of a patient's primary care provider prior to the administering of any immunization. If the patient identifies such primary care provider to the pharmacist, the pharmacist shall notify the primary care provider, by written or electronic communication, as soon as reasonably possible thereafter that the immunization was administered.
- B. This Section shall not apply to the administering of an immunization pursuant to R.S. 37:1218. (Section added by Act 651 of the 2012 Regular Session; amended by Act 769 of the 2014 Regular Session; Act 271 of the 2022 Regular Session)

## §1218.2. Administration and treatment for human immunodeficiency virus

- A. For the purposes of this Section, the following terms have the meaning ascribed to them:
  - (1) "Department" means the Louisiana Department of Health.
  - (2) "Human immunodeficiency virus", hereinafter referred to as "HIV", means a virus that attacks the body's immune system which, if not treated, can develop into acquired immunodeficiency syndrome.
  - (3) "Post-exposure prophylaxis" means an emergency regimen comprising highly active antiretroviral therapy with baseline and follow-up HIV testing, which should be used within a certain amount of time after potential exposure.
  - (4) "Pre-exposure prophylaxis" means a prophylactic regimen that includes medication, regular counseling, and regular screening.
- B. (1) A pharmacist may dispense and administer up to a thirty day supply of HIV pre-exposure prophylaxis and a twenty-eight day course of HIV post-exposure prophylaxis to any person age seventeen or older pursuant to rules promulgated by the department if there is no prescription drug order.
  - (2) A pharmacist may perform a rapid HIV test at the pharmacy in a private, secured location or may order laboratory testing for HIV infection for any person age seventeen or older pursuant to rules promulgated by the department.
  - (3) A pharmacist shall administer any tests performed pursuant to this Section in a private location within the pharmacy, and shall ensure patient confidentiality, including storing all records and documents regarding a patient's test results for HIV in a secured location that is not easily accessible by other employees in the pharmacy.
- C. (1) The department shall promulgate rules in accordance with the <u>Administrative Procedure Act</u> to implement the provisions of this Section.
  - (2) The department shall consult with an expert panel to advise it in promulgating administrative rules to implement the provisions of this Section. The administrative rules shall be promulgated by March 2025.

- (a) The expert panel shall integrate and coordinate expertise relative but not limited to testing, referrals, prescribing, and reimbursement for HIV pre-exposure prophylaxis and HIV post-exposure prophylaxis.
- (b) The expert panel shall be composed of the following members who shall serve without compensation:
  - (i) A representative from the Louisiana Department of Health, bureau of infectious diseases.
  - (ii) An infectious disease physician to be selected by the department.
  - (iii) A primary care physician who has experience managing patients who utilize HIV medications to be selected by the department.
  - (iv) Two pharmacists to be selected by the department.
  - (v) A representative from the Louisiana Board of Pharmacy.
  - (vi) A representative from the Louisiana State Board of Medical Examiners.
- (3) The rules promulgated by the department shall include requirements relating to the testing, screening, and treatment of patients. At a minimum, the rules shall require the pharmacist to do all of the following:
  - (a) Complete a training program approved by the department on the use of HIV pre-exposure prophylaxis and HIV post-exposure prophylaxis prior to exercising the authority provided for in this Section. The training shall include but not be limited to all of the following:
    - (i) Financial assistance programs for HIV pre-exposure prophylaxis and HIV post-exposure prophylaxis.
    - (ii) Strategies to access state and federal resources to provide the same level of care for patients regardless of insurance coverage status.
  - (b) Document a focused assessment of the patient following best practices and guidelines for preventing HIV.
  - (c) Document steps to obtain consent, order, process, evaluate, interpret, and discuss results with patients of any HIV laboratory tests authorized in the rules promulgated by the department.
  - (d) Identify the nature and obligations for successful HIV pre-exposure prophylaxis or HIV post-exposure prophylaxis, as required by the patient, and the importance of timely testing for HIV and related complications and comorbid conditions.
- (4) The rules promulgated by the department shall include procedures for the timely notification of the patient's primary care provider of the services provided, or when a patient does not have a primary care provider, documentation of a good faith effort to refer the patient to a primary care provider.
- D. A pharmacist authorized to provide a service relative to HIV pre-exposure and post-exposure prophylaxis shall be reimbursed at the same rate as any other participating healthcare provider providing such service in accordance with the patient's health coverage plan.
- E. This Section shall not be construed to require a health coverage plan or a third-party administrator or pharmacy benefit manager to reimburse a pharmacist or pharmacy as an in-network or a preferred provider.
- F. The provisions of this Section may apply to coverage under a group or individual health coverage plan provided to a resident of this state regardless of whether the health coverage plan policy, contract, or other agreement is delivered, issued for delivery, or renewed in this state.

(Section added by Act 711 of the 2024 Regular Session)

## §1219. Affordable alternative options to prescription drugs

- A. Pharmacists may provide sufficient information to a patient to allow him an opportunity to consider all relevant options when acquiring prescription medications, including but not limited to the cost and clinical efficacy of a more affordable alternative if one is available and the ability to pay cash if a cash payment for the same drug is less than an insurance copayment or deductible payment amount.
- B. Failure to comply with this Section shall not constitute a violation of a pharmacist's standard of care regarding the patient. No pharmacist shall be penalized by the board or any third party for failure to comply with the provisions of this Section.
- C. (1) No pharmacy or pharmacist shall be bound to terms of a contract with a pharmacy benefit manager or other entity that administers prescription drug benefits that prevent disclosure of the information provided for in this Section.
  - (2) On or after August 1, 2018, any contract provision prohibiting the communication provided for in this Section shall be severable from the contract and considered void and not enforceable in Louisiana.
- D. (1) Any pharmacy or pharmacist who has a contract, either directly or through a pharmacy service administration organization, with a pharmacy benefit manager administering any type of drug or pharmacy benefit plan to provide covered drugs, devices, or services at a contractual reimbursement rate may decline to provide a covered drug, device, or service if the pharmacy or pharmacist will be or is paid less than the acquisition cost for the covered drug, device, or service.

- (2) If the pharmacy or pharmacist declines to provide the drug, device, or service as authorized in this Subsection, then the pharmacy or pharmacist shall provide the customer with adequate information as to where the prescription for the drug, device, or service may be filled.
- (3) No pharmacy benefit manager, pharmacy services administration organization, or any person acting for or on behalf of a pharmacy benefit manager or pharmacy services administration organization shall cancel any contract with the pharmacy or pharmacist, sue for breach of contract, use the decision to decline as a cause for not renewing the contract, or retaliate against or penalize the pharmacy or pharmacist in any way.
- E. The commission of any act prohibited by this Section shall be considered an unfair method of competition and unfair practice or act which shall subject the violator to any and all actions, including investigative demands and private actions, remedies, and penalties, provided for in the Unfair Trade Practices and Consumer Protection Law, R.S. 51:1401 et seq.
- F. Any provision of a contract that is contrary to any provision of this Section shall be null, void, and unenforceable in this state.

(Section added by Act 317 of the 2018 Regular Session; amended by Act 161 of the 2019 Regular Session)

#### [End of Part III]

### Part IV. Permit Requirements

## §1221. Unlawful operation

- A. No person shall open, establish, operate, or maintain a pharmacy, located within this state unless the pharmacy is issued a permit by the board.
- B. No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy located out-of-state unless the pharmacy is issued a permit by the board.
- C. No permit to operate a pharmacy shall be granted or renewed unless evidence satisfactory to the board ensures that a pharmacist in the state where the permit is issued and pharmacy is located will be on duty during normal hours as administratively defined.

## §1222. Qualifications

- A. A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.
- B. Each pharmacy shall ensure accessibility to pharmacy primary care for the public as defined by the board.
- C. Each pharmacy permitted by the board may designate a registered agent in this state for service of process.
- D. Any such person who does not so designate a registered agent shall be deemed to have designated the secretary of state to be its agent, upon whom may be served all legal process in any action or proceeding against such pharmacy.
- E. A permit to operate a pharmacy shall not be transferable.

## §1223. Classifications

- A. The board shall determine the permit classifications of all persons permitted under this Part, and establish minimum standards for such persons.
- B. The board shall establish the criteria that each permit holder must meet to qualify for a permit in each classification. The board may issue a permit with varying restrictions to such persons where the board deems it necessary.

## §1224. Compounding and filling of prescriptions; absence of pharmacist

- A. In each pharmacy there shall be a pharmacist on duty at all times. The filling, compounding, and dispensing of prescriptions, and the making of pharmacy-generated drugs, shall be accomplished in compliance with standards established by the board by rule. The performance of these activities shall be limited to pharmacists and pharmacy interns, pharmacy technicians, and pharmacy technician candidates acting under the supervision of a pharmacist.
- B. If the pharmacist should find it necessary to be temporarily absent, leaving the prescription department unattended either by a pharmacist or a pharmacy technician, then the prescription department shall be closed.
- C. The board shall establish criteria for the temporary absence of a pharmacist from the prescription department.
- D. Notwithstanding any provision of law to the contrary, after the pharmacist or pharmacy technician has complied with all duties imposed upon him by law regarding a prescription, a cashier or other clerical person may lawfully deliver the drug or device and collect payment therefor.

E. A prescription may be filled, compounded, and dispensed at the permitted pharmacy which first received the prescription or at any other permitted pharmacy to which the prescription is properly transferred from the originating pharmacy. A prescription may be properly transferred through the transfer of prescription information from one pharmacy to another manually or through an electronic transfer using an electronic file updated on a real-time on-line basis and shared by two or more pharmacies. Electronic transfers of prescriptions shall be permitted regardless of whether or not the pharmacy from which the prescription is transferred is open for business.

(Section amended by Act 83 of the 2000 First Extraordinary Session; Act 168 of the 2013 Regular Session)

## §1224.1. Filling of additional refills in anticipation of authorization

Notwithstanding any provision of law to the contrary, when all refills authorized on an original prescription have been dispensed, additional prescription refills may be added to the original prescription and compounded, filled, and labeled prior to the receipt of authorization for the additional refills from the prescriber, provided that no additional prescription refill may be transferred to the patient or the patient's representative prior to the receipt of such authorization from the prescriber, and provided that the date and time of such authorization and the name of the person transmitting the authorization is maintained in the prescription record and is immediately accessible on-line and retrievable in a hard copy within seventy-two hours of request.

## §1225. Labeling of drugs and prescriptions

All receptacles containing compounded or filled prescriptions shall bear a label showing the prescription number, the initials of the pharmacist actually and personally responsible for drug regimen review, filling, compounding or dispensing the prescription, adequate directions for use unless stated otherwise by the prescriber, the date of its compounding or filling, and the name of the pharmacy. Each permitted pharmacy shall post a legibly written list of names of all pharmacists dispensing medication in the pharmacy for viewing by its employees. Any such label shall include all information required by federal law.

## §1226. Prescription; name of patient

No pharmacist or dispensing physician shall fill any prescription unless the name of the patient and the trade name, or the generic name, or the most commonly used name of the medication or device appears on the label, unless otherwise specified by the practitioner.

# §1226.1. Communication to the prescriber

- A. No later than five business days following the dispensing of a biological product, the dispensing pharmacist or his designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer.
- B. The required communication included in Subsection A of this Section may be done by any means.
- C. No communication shall be required if there is no interchangeable or therapeutically equivalent biological product approved by the United States Food and Drug Administration for the product prescribed, or if the prescription is a refill not changed from the product dispensed on the prior filling of the prescription.
- D. Nothing in this Section shall create a cause of action against the prescriber and the dispensing pharmacist or his designee for a communication as required pursuant to this Section.
- E. No communication shall be required pursuant to this Section if the prescriber indicates "dispense as written." (Section added by Act 391 of the 2015 Regular Session; amended by Act 206 of the 2018 Regular Session)

# §1226.2. Prescription drug returns, exchanges, and redispensing; donation requirements; authority to promulgate rules; limitation of liability

- A. All drugs dispensed on prescription to a patient shall be accepted for return, exchange, or redispensing by a charitable pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed including but not limited to:
  - (1) In a hospital with a permitted pharmacy on site, drugs may be returned to the pharmacy in accordance with good professional practice standards.
  - (2) Any person, including a drug manufacturer, hospital, health care facility, or governmental entity may donate prescription drugs to a charitable pharmacy for relabeling and dispensing to the indigent, free of charge, pursuant to a valid prescription order.
- B. Donations of prescription drugs to a charitable pharmacy are subject to the following requirements:
  - (1) The charitable pharmacy may accept drugs in their original sealed and tamper-evident packaging, including drugs packaged in single-unit doses, including blister packs. These drugs may be dispensed when the outside packaging is opened if the single-unit dose packaging is intact, subject to the provisions of Paragraph (B)(2) of this Section.

- (2) The pharmacist in charge of the charitable pharmacy shall determine if the drug is not adulterated or misbranded and is safe to dispense. No product where the integrity of the medication cannot be assured shall be redispensed by the pharmacist of the charitable pharmacy.
- (3) The donor shall execute a form stating the donation of the drugs. The pharmacy shall retain that form along with other acquisition records.
- (4) The patient's name, prescription number, and any other identifying marks shall be obliterated from the packaging prior to redispensing the medication to another patient.
- (5) The drug name, strength, and expiration date shall remain on the medication package label. The redispensed medication shall be assigned the expiration date stated on the package.
- (6) Expired drugs accepted by a charitable pharmacy shall not be redispensed.
- (7) The charitable pharmacy shall comply with all state and federal laws regarding controlled substances.
- (8) No drug dispensed through a charitable pharmacy shall be eligible for reimbursement from the Medicaid Pharmacy Program.
- (9) In the event that a charitable pharmacy in the closest proximity to the donor refuses the donation, such refusal shall be documented by the donor, who then may make the donation to the Department of Public Safety and Corrections Corrections Services for distribution to the penal institution pharmacies under its authority.
- C. The board shall have the authority to promulgate rules and regulations in accordance with the <u>Administrative</u> <u>Procedure Act</u> for the purpose of administering the provisions of this Section.
- D. (1) No person, including a drug manufacturer, healthcare facility, or governmental agency who donates prescription drugs to a charitable pharmacy, as well as the charitable pharmacy, any pharmacist who originally dispensed the donated prescription drugs, any pharmacist dispensing donated prescription drugs, or the Louisiana Board of Pharmacy shall be subject to any professional disciplinary action, criminal prosecution, liability in tort or other civil action for injury, death, or loss to person or property related to the donating, accepting, or dispensing of donated prescription drugs.
  - (2) No pharmaceutical manufacturer shall be liable for any claim or injury arising from the transfer of any prescription drug pursuant to the provisions of this Section, including but not limited to liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.
- E. For purposes of this Section "charitable pharmacy" means the practice of a pharmacy at a site where prescriptions are dispensed by a charitable organization free of charge to appropriately screened and qualified patients.
- F. A hospital, health care facility, or governmental entity enrolled in the Medicaid program shall attempt to donate all unused or surplus prescription drugs meeting the criteria in Subsections A and B of this Section to charitable pharmacies. The provisions of this Subsection shall not apply to any hospital, health care facility, or governmental entity owned by or operated by an agency or department of the executive branch of the state.
- G. In the event such hospital, health care facility, or governmental entity does not have a charitable pharmacy within twenty miles of its location, the charitable pharmacy shall have the obligation to obtain those prescription drugs. In the event the charitable pharmacy is unable to make such arrangements, there shall be no such requirement on the part of the hospital, health care facility or governmental entity to donate the drugs.
- H. Notwithstanding any other provision of law to the contrary, a faith-based charitable pharmacy shall not be required to accept any prescription drugs it deems to conflict with its faith values.
- I. For the purpose of this Section, "governmental entity" shall mean a health care facility owned and operated by a political subdivision of the state.

(Section added by Act 811 of the 2004 Regular Session; amended by Acts 643 and 797 of the 2006 Regular Session; Act 206 of the 2018 Regular Session)

# §1226.3. Prescription drugs; returns, exchanges and redispensing in pharmacies serving certain correctional facilities; authority to promulgate rules

- A. Except as provided in Subsection B of this Section, all drugs dispensed on prescription to an offender in the custody of the Department of Public Safety and Corrections, or in the custody of a local law enforcement office or department, may be accepted for return, exchange or re-dispensing by a pharmacy operated by or under contract with the department or by a pharmacy authorized by the board to provide prescriptions to a local law enforcement office or department.
- B. The pharmacist-in-charge of the pharmacy shall determine that the returned drug is not adulterated, expired, or misbranded and is safe to dispense. No product shall be redispensed by the pharmacist if the integrity of the medication cannot be assured. A drug that can be dispensed only to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements shall not be accepted or redispensed under the provisions of the program provided for in this Section.

- C. No pharmaceutical manufacturer shall be liable for any claim or injury arising from the redispensing of any prescription drug pursuant to the provisions of this Section, including but not limited to liability for failure to transfer or communicate product or consumer information regarding the redispensed drug, as well as the expiration date of the redispensed drug.
- D. The Louisiana Board of Pharmacy shall have the authority to promulgate rules in accordance with the <u>Administrative Procedure Act</u> for the purpose of administering the provisions of this Section.

(Section added by Act 315 of the 2011 Regular Session; amended by Act 310 of the 2016 Regular Session)

### §1226.4. Chart orders; bidirectional transmission; renewal

- A. The institutional facility is the only party to the prescription drug chart order that shall be required to maintain a copy of the prescriber's signature unless otherwise required by federal law.
- B. Bidirectional electronic transmission of chart orders between the institutional facility and the pharmacy shall be permitted when transmission occurs in a manner that complies with rules promulgated by the Centers for Medicare and Medicaid Services and other federal rules or regulations.
- C. Renewal of ongoing chart orders shall be signed by the prescriber at the appropriate time interval based on facility type and federal regulations, state law, or rule. Unless otherwise indicated, chart orders shall be ongoing until such time as the practitioner discontinues the order and such discontinuation is communicated to the pharmacy.
- D. The board may promulgate rules to recognize and regulate the use of chart orders that are not otherwise specifically provided for in this Section.

(Section added by Act 602 of the 2018 Regular Session)

### §1228. Equipment required of pharmacy

The board shall determine, by regulation, all standards for professional, technical, equipment and any other requirements deemed necessary for a pharmacy to possess, in order to operate in the best interest of the health, safety and welfare of the public.

## §1229. Records of prescription; retention; inspection

- A. There shall be kept in every pharmacy a suitable book, file, or electronic record keeping system in which shall be preserved, for a period of not less than two years, or such longer period as may be mandated by other applicable law or regulation, a record of every prescription filled, compounded, or dispensed. Such book, file, or electronic record of prescriptions shall be open to inspection by the board, or its authorized agents or employees during hours of operation.
- B. Records maintained electronically pursuant to this Section shall contain all information required in a manual records system. The electronic record keeping system shall be capable of producing a hard copy printout of the prescription record within seventy-two hours of request.
- C. The board shall not impose stricter record keeping requirements on electronic files than those requirements imposed on manual systems.
- D. As used in this Section, "electronic record keeping system" means a system, including machines, methods of organization, and procedures, that provides input, storage, processing, communications, output, and control functions for digitized representations of original prescriptions.

## §1230. Renewal of permits; expiration; reinstatement

- A. (1) Each pharmacy issued a permit by the board shall apply for renewal at the time designated by the board and shall pay a fee specified by the board.
  - (2) (a) (i) The board shall assess on each pharmacy permit renewal required by this Section an additional fee of one hundred dollars per year to be designated as the "pharmacy education support fee."

    This fee shall be dedicated and allocated as specified in this Paragraph to an accredited school of pharmacy of a public university in this state. The board shall include on each permit renewal form issued to a pharmacy an optional election whereby the pharmacy may elect not to remit the one hundred dollar pharmacy education support fee.
    - (ii) For purposes of this Paragraph, "accredited" shall mean possession of current accreditation from the Accreditation Council for Pharmacy Education.
    - (b) The board shall disburse all monies collected pursuant to this Paragraph to an accredited public university pharmacy school in this state on or before April first annually. The public university pharmacy school shall utilize these monies solely for the benefit of its pharmacy education program and the expenditure of such funds shall be approved by the board of supervisors of the university system of which the university is a member. The funds collected pursuant to this Paragraph shall be in addition to any other monies received by the university that operates the pharmacy school and are

intended to supplement and not replace, displace, or supplant any other funds that the university receives from the state or from any other source.

- B. Any person who desires to continue to operate or maintain a pharmacy within or outside of the state shall file an application with the board for renewal in such form and contain such information as the board may require and complete such other requirement as deemed necessary by the board.
- C. Application for renewal of a permit shall be made available on or before a date designated by the board. If a permit holder fails to make application to the board for renewal of his permit within a period determined by the board, the existing permit shall expire and become null and void.
- D. In order to reinstate an expired permit, the permit holder shall meet requirements established by the board. (Section amended by Act 357 of the 2012 Regular Session; Act 298 of the 2015 Regular Session; Act 202 of the 2020 Regular Session)

### §1231. Agreements; notifications

- A. The board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the permitting and inspection of entities located in this state and those located outside the state
- B. All permitted persons shall report to the board the occurrence of any of the following:
  - (1) Permanent closing.
  - (2) Change of ownership, management, location, or pharmacist-in-charge of a pharmacy.
  - (3) Any theft or significant loss of drugs or devices.
  - (4) Any known conviction of any employee of any state or federal drug laws.
  - (5) Disasters, accidents, or any theft, destruction, or loss of records required to be maintained by state or federal law.

## §1232. Nonresident pharmacy

- A. A pharmacy located outside this state which does business in this state within the meaning of this Chapter shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."
- B. A nonresident pharmacy granted a nonresident pharmacy permit by the board shall disclose to the board the location, names, and titles of all principal corporate officers, as well as the owner's managing officer and pharmacist-in-charge. A report containing this information shall be made to the board with each renewal application and within thirty business days after any change of office, corporate officer, or within ten business days of the departure of the prior owner's managing officer or pharmacist in charge.
- C. The nonresident pharmacy shall maintain at all times authorization to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to seeking a permit from the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located, as well as any other state pharmacy licensing agency or any agent thereof, and any inspection reports produced by the federal Food and Drug Administration or the federal Drug Enforcement Administration. Thereafter, the nonresident pharmacy granted a permit shall submit to the board a copy of any subsequent inspection report on the pharmacy conducted by the regulatory or licensing body of the state in which it is located, or by any other state pharmacy licensing agency, or any agent thereof, or by the federal Food and Drug Administration or the federal Drug Enforcement Administration. In addition to or in lieu of an inspection by the regulatory or licensing body of the state in which it is a resident, or any agent thereof, the nonresident pharmacy shall be subject to an inspection by the board. When the board conducts an inspection of a nonresident pharmacy, the board shall recover its expenses from the nonresident pharmacy in addition to the applicable permit fee authorized by this Chapter.
- D. A nonresident pharmacy granted a nonresident pharmacy permit by the board shall maintain records of any controlled substances or dangerous drugs or devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.
- E. Records for all prescriptions and products delivered into the state shall be readily retrievable from the other prescription records of the nonresident pharmacy and shall be in compliance with all federal laws and regulations as may be required by this state.

(Section amended by Act 164 of the 2006 Regular Session; Act 282 of the 2013 Regular Session; Act 202 of the 2020 Regular Session)

[End of Part IV]

## Part V. Discipline

## §1241. Refusal, restriction, suspension, or revocation of license

- A. The board may, after due notice and hearing, assess a fine not to exceed the sum of five thousand dollars for each offense, refuse to license, register, certify, or permit any applicant, refuse to renew the license or permit of any person, or may revoke, summarily suspend, suspend, place on probation, reprimand, issue a warning against the person who was issued the license, registration, certificate, permit or any other designation deemed necessary to engage in the practice of pharmacy upon proof that the person:
  - (1) Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.
  - (2) Attempted to or obtained a license, registration, certificate, permit or any other designation deemed necessary to engage in the practice of pharmacy by fraud or misrepresentation.
  - (3) Committed repeated occasions of negligence or incompetence in the practice or assistance in the practice of pharmacy.
  - (4) Has been convicted of a felony that the board finds is directly related to the practice of pharmacy pursuant to R.S. 37:2950 in the courts of any state, territory, or country. Conviction, as used in this Paragraph, shall include a finding or verdict of guilty, an admission of guilt, or a plea of *nolo contendere*.
  - (5) Is habitually intemperate or is addicted to the use of alcohol or habit-forming drugs.
  - (6) Has had his license, permit, certification, registration or any other designations deemed necessary to engage in the practice of pharmacy revoked or suspended, or has had other disciplinary action taken, or has had his application for licensure refused, revoked, or suspended by the proper authorities of another state, territory, or country based upon conduct by the licensee similar to conduct that would constitute grounds for action as defined in this Section.
  - (7) Has failed to report to the board any adverse action taken by another licensing jurisdiction, government agency, law enforcement agency, or court for conduct that would constitute grounds for action as defined in this Section.
  - (8) Has failed to report to the board the surrender of a license, permit, certification, registration or any other designation deemed necessary to engage in the practice of pharmacy in another state or jurisdiction while under disciplinary investigation by any of those authorities or bodies for conduct that would constitute grounds for action as defined in this Section.
  - (9) Has failed to report to the board any adverse judgment, settlement, or award arising from a malpractice claim arising related to conduct that would constitute grounds for action as defined in this Section.
  - (10) Has departed from or failed to conform to the minimal standards of acceptable and prevailing pharmacy practice, whether or not actual injury to a patient has occurred.
  - (11) Has committed fraud by a licensee in connection with the practice of pharmacy, including, but not limited to Medicaid fraud, Medicare fraud, or insurance fraud.
  - (12) Has engaged, or aided and abetted a person to engage in the practice of pharmacy without a license, registration, certificate, permit or any other designation deemed necessary to engage in the practice of pharmacy.
  - (13) Has failed to pay the costs assessed in a disciplinary hearing.
  - (14) Has engaged in any conduct that subverts or attempts to subvert any examination or the administration of any examination authorized under this Chapter.
  - (15) Has evaded, or assisted, directly or indirectly, another person in evading any local, state or federal laws or regulations pertaining to the practice of pharmacy.
  - (16) Has divulged or revealed confidential information or personally identifiable information to a person other than as authorized by state or federal law or the rules of the board.
  - (17) (a) Has knowingly selected an equivalent drug product if the practitioner or authorized prescriber instructs otherwise by either of the following:
    - (i) On a written prescription drug order, handwriting a mark in a check-off box labeled with "Dispense as Written", or the abbreviation "DAW", or both, and personally handwriting his signature on a printed-single-signature line. A written prescription drug order shall indicate the practitioner's or authorized prescriber's name, licensure designation, and practice affiliation, if any.
    - (ii) On an oral prescription, verbally indicating that a specific brand-name drug or product is ordered by the practitioner or authorized prescriber or his agent. The pharmacist shall note such information on the file copy of the prescription.

- (b) The patient shall be informed of, and consent to, the equivalent drug product interchange when the practitioner or authorized prescriber permits the equivalent drug product interchange.
- (c) In order to comply with 42 CFR 447.331<sup>3</sup>, for prescriptions reimbursable by Medicaid, the practitioner or authorized prescriber may prohibit equivalent drug product interchange only by handwriting the words "brand medically necessary" or "brand necessary" directly on the written prescription drug order or on a sheet attached to the prescription. Recipients of Medicaid prescription benefits demonstrate implied consent by their participation in the program, provided the practitioner or authorized prescriber has not prohibited equivalent drug product interchange in the manner specified in Subparagraph (a) of this Paragraph.
- (18) Has knowingly received or possessed any drug or device that is, or has been, adulterated or misbranded, or knowingly or intentionally delivered or proffered any such product to the public.
- (19) Has engaged in false, misleading, or fraudulent advertising as defined by the board.
- (20) Has solicited professional practice by means of providing physicians or other practitioners with prescription blanks imprinted with any material referring to a pharmacy or pharmacist.
- (21) Has advertised by including any reference, direct or indirect, to any controlled dangerous substances as provided for in Schedules II, III, IV, and V of R.S. 40:964.
- (22) Has failed to furnish to the board, its investigators, or representatives any information legally requested by the board.
- (23) Has used an independent contractor to provide marketing services for the pharmacy to any practitioner, authorized prescriber, or prospective customer in Louisiana in exchange for compensation unless the compensation paid is an amount set in advance, consistent with fair market value, and not calculated based on the volume or value of actual prescriptions filled by the pharmacy.
- (24) Has dispensed or distributed any drug or device to any patient pursuant to a prescription written by a practitioner or a member of the practitioner's group practice if the practitioner or an immediate family member of the practitioner has a direct or indirect financial relationship with the dispensing or distributing pharmacy, unless the financial relationship meets all of the requirements of R.S. 37:1745. Nothing in this Paragraph shall prohibit a practitioner or an immediate family member of the practitioner from having an ownership interest in a pharmacy.
- B. The board may require a pharmacy to produce any information the board deems reasonably necessary to investigate alleged violations of and otherwise enforce Paragraphs (A)(23) and (24) of this Section.
- C. In addition to the disciplinary action or fine assessed by the board, the board may assess all costs incurred in connection with the proceedings, including but not limited to investigator, stenographer, and attorney fees.
- D. Each day on which a violation occurs is a separate violation for the purposes of this Part.
- E. The board may, by regulation, defer action with regard to an impaired licensed, registered, or certified person who voluntarily signs an agreement, in a form satisfactory to the board, agreeing not to practice pharmacy and to enter an approved treatment and monitoring program in accordance with this Section, provided that this Section should not apply to a licensee who has been convicted of, pleads guilty to, or enters a plea of nolo contendere to a felonious act prohibited by or a conviction relating to a controlled substance in a court of law of the United States or any state, territory, or country.
- F. The board retains jurisdiction over all such unlicensed, uncertified, or unpermitted persons relative to violations of and enforcement of the provisions of this Chapter. However, nothing contained in this Chapter shall prevent any licensed practitioner of medicine, dentistry, or veterinary medicine from compounding, dispensing, administering to, or supplying his patients with the necessary drugs and medicines for their use.
- G. Any individual who, after a hearing, shall be found by the board to have unlawfully engaged in the practice of pharmacy shall be subject to a fine not to exceed the sum of five thousand dollars to be imposed by the board. Each such violation of this Chapter or the regulations promulgated hereunder pertaining to unlawfully engaging in the practice of pharmacy shall also constitute a misdemeanor punishable upon conviction by a fine of no more than five hundred dollars or by imprisonment for no more than six months, or both.

(Section amended by Acts 852 and 1031 of the 2001 Regular Session; Act 164 of the 2006 Regular Session; Act 409 of the 2015 Regular Session; Act 644 of the 2024 Regular Session)

#### §1242. Violations; penalties

Any person who shall practice or assist in the practice of pharmacy without a currently valid license, registration, certificate, permit, or any other designation deemed necessary to engage in the practice of pharmacy shall be guilty of a misdemeanor and upon conviction shall be fined not less than one hundred dollars and not more than one thousand dollars, or imprisoned for not more than six months, or both, and, in addition, may have his license and/or permit restricted, suspended, or revoked by the board. Each act of such unlawful practice shall constitute a distinct and separate offense.

## §1243. Enforcement of Chapter through court action

The board may institute any action in a court of competent jurisdiction to enforce compliance with any provision of this Chapter or with any regulation, subpoena, or order of the board made pursuant to the provisions of this Chapter.

#### §1244. Injunction; penalty; attorney fees; costs

- A. The board may seek in any court of competent jurisdiction a writ of injunction enjoining any person from practicing or assisting in the practice of pharmacy, until such person obtains the necessary license, registration, certificate, or permit under the provisions of this Chapter. This injunction shall not be subject to being released upon bond.
- B. In the suit for an injunction, the board may demand of the defendant a penalty of not more than five thousand dollars, as well as reasonable attorney fees and the costs of court. This judgment for penalty, attorney fees and costs may be rendered in the same judgment in which the injunction is made absolute.
- C. The trial of the proceeding by injunction shall be summary and by the judge without a jury.
- D. Nothing herein shall be construed as barring criminal prosecutions for violations of this Chapter.

## §1245. Investigation, notice, and hearing

- A. The board may upon its own motion, or upon a verified written complaint of any person setting forth facts which, if proved, would constitute grounds for:
  - (1) Refusal to issue or renew.
  - (2) Suspension or revocation of any such license, certificate, or permit, investigate the action of any person applying for, holding or claiming to hold, any such license, registration, certificate, or permit, or other designation deemed necessary to engage in the practice of pharmacy.
- B. The board shall, at least thirty days prior to the date set for the hearing, notify in writing the applicant for, or holder of, any such license, registration, certificate, permit, or any other designation deemed necessary to engage in the practice of pharmacy, of any charges made, and shall afford the accused person an opportunity to be heard in reference thereto. The written notice may be served by delivering it personally to the accused person, or by mailing it by registered or certified mail to the accused person's last address on record with the board. At the time and place fixed in the notice, the board shall proceed to hear the charges. The accused person, the complainant, and a representative of the board, shall each have an opportunity to present in person, or by counsel, such matters as may be pertinent to the charges and to any defense thereto. The board may continue such hearing from time to time, and from place to place, as may be necessary or proper.
- C. If an application for any license, registration, certificate, permit, or any other designation deemed necessary to engage in the practice of pharmacy or renewal thereof, is refused, or if any license, registration, certificate, permit, or any other designation deemed necessary to engage in the practice of pharmacy is restricted, suspended, or revoked, the board shall notify the applicant thereof, or the holder thereof, in writing, of its decision and the reason for such action.

# §1246. Issuance of subpoenas; witnesses; production of records; maintenance of confidentiality

- A. The board, or its designated agent, may issue subpoenas or subpoenas duces tecum requiring the attendance and testimony of witnesses and the production of any evidence or documentation that relates to any matter properly under investigation or in question before the board or committee conducting the hearing or investigation.
- B. Each witness who appears before the board pursuant to subpoena shall receive for his attendance the fees and mileage provided for witnesses in civil cases in the courts of this state.
- C. No subpoena shall be issued at the request of a party other than the board unless the fees and mileage provided for in Subsection B of this Section are deposited to the board in advance.
- D. In case of refusal to obey a subpoena or subpoena duces tecum issued to any person or entity, the board may apply to any district court within the jurisdiction where the inquiry is conducted or within the jurisdiction where such person is domiciled, resides, or transacts business, to issue to such person or entity an order requiring him to appear before the board, its members, agent, or agency, to produce evidence if ordered or to give testimony concerning the matter under investigation or in question.
- E. Notwithstanding any privilege or confidentiality recognized by law, no person engaging or assisting in the provision of pharmacy services with which such pharmacist is affiliated shall, acting under any such privilege, fail or refuse to respond to a lawfully issued subpoena of the board for any pharmaceutical or medical information, testimony, records, data, reports or other documents, tangible items, or information relative to any patient served by any such pharmacist or person assisting a pharmacist under investigation. However, the identity of any patient identified in or such records or information shall be maintained in confidence by the board and shall be deemed a privilege of confidentiality existing in favor of any such patient. For the purpose of maintaining such

confidentiality of patient identity, the board shall cause any such records or the transcript of any such testimony to be altered so as to prevent the disclosure of the identity of the patient to whom such records or testimony relates.

## §1247. Rehearings

A decision or order in a case of adjudication shall be subject to rehearing, reopening, or reconsideration by the board within ten days from the date of its entry.

## §1248. Review of board orders

- A. Any person to whom the board has refused to issue a license, registration, certificate, or permit, or any other designation deemed necessary to engage in the practice of pharmacy, or whose license, registration, certificate, or permit, or any other designation deemed necessary to engage in the practice of pharmacy has been suspended or revoked, may appeal from the decision and order of board to the Nineteenth Judicial District Court.
- B. Absent agreement of counsel for all parties, no stay of enforcement of a decision issued by the board during pendency of an appeal pursuant to the provisions of this Section shall be granted unless the district court finds that the applicant has established that the issuance of the stay does not:
  - (1) Threaten harm to other interested parties, including persons for whom the applicant may render pharmacy services; or
  - (2) Constitute a threat to the health and welfare to the citizens of the state.
- C. No stay shall be granted *ex parte*. The court shall schedule a hearing on the request for a stay order within ten days from filing of the request. The decision shall be rendered within five days after the conclusion of the hearing.

# §1249. Reinstatement or re-issuance of license, registration, certificate, permit, or any other designation deemed necessary to engage in the practice of pharmacy

- A. At any time after the suspension or revocation of any such license, registration, certificate, permit, or any other designation deemed necessary to engage in the practice of pharmacy, the board may restore the license, registration, certificate, permit, or any other designation deemed necessary to engage in the practice of pharmacy to the accused person, but only at an official meeting of the board, after written notice, and by vote of a majority of the members of the board present and voting. If a license, registration, certificate, permit, or any other designation deemed necessary to engage in the practice of pharmacy is reinstated or reissued following previously applied sanctions relative to a violation of this Chapter, said reinstatement or reissuance shall have affixed thereto an attachment or addendum specifically setting forth any restrictions placed upon said reinstated or reissued license, registration, certificate, permit, or any other designation deemed necessary to engage in the practice of pharmacy by the board.
- B. In case of reinstatement, the holder of the reinstated license, registration, certificate, or permit holder shall pay all costs or fines, or both, and a reinstatement fee as provided for in the board's fee schedule established pursuant to R.S. 37:1184<sup>2</sup>.

## §1250. Exceptions

- A. Nothing in this Chapter shall be construed to prevent or restrict the practice of nursing by a licensed registered nurse or an advanced practice registered nurse in accordance with <u>R.S. 37:911</u> et seq., 1031 through 1034<sup>4</sup>, or any other laws, rules, or regulations governing the practice of nursing in the state of Louisiana.
- B. Nothing in this Chapter shall apply to a facility which engages solely in the distribution of dialysate, drugs, or devices necessary to perform home kidney dialysis to patients with end-stage renal disease if all of the following criteria are met:
  - (1) The dialysate, drugs, or devices are approved or cleared by the United States Food and Drug Administration as required by federal law.
  - (2) The dialysate, drugs, or devices are lawfully held by a manufacturer or manufacturer's agent that is properly registered with the board as a distributor of legend drugs or legend devices.
  - (3) The dialysate, drugs, or devices are held and delivered in their original, sealed packaging from the manufacturing facility.
  - (4) The dialysate, drugs, or devices are delivered only by the manufacturer or the manufacturer's agent and only upon the receipt of a physician's order.
  - (5) The manufacturer or manufacturer's agent delivers the dialysate, drugs, or devices directly to any of the following parties:
    - (a) A patient with end-stage renal disease, or his designee, for self-administration of the dialysis therapy by the patient.
    - (b) A healthcare provider or institution for administration or delivery of the dialysis therapy to a patient with end-stage renal disease.

#### [End of Part V]

### Part VI. Disclosure of Prescription Drug Price Information

(This new Part VI, composed of Section 1251, was added by Act 236 of the 2017 Regular Session, effective June 14, 2017. Subsequent amendments are noted herein.)

### §1251. Disclosure of prescription drug price information

- A. (1) The Louisiana Board of Pharmacy shall develop a website to contain prescription drug price information to be made available to Louisiana prescribers on the board's website with a dedicated link that is prominently displayed on the board's home page, or by a separate easily identifiable internet address.
  - (2) The website shall include, at a minimum, the following data elements, separated by therapeutic category:
    - (a) Name of the product.
    - (b) Whether the drug is a brand name or a generic.
    - (c) Drug strength.
    - (d) Per-unit wholesale acquisition cost of the drug.
    - (e) Any disclaimers deemed appropriate by the board.
  - (3) When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a prescriber, his designee, or any member of his staff, the marketer may disclose the website's internet address and inform the prescriber that he may access the website to obtain information on the cost of prescription drugs. The provisions of this Section shall only apply to pharmaceutical marketing engaged in by a pharmaceutical marketer and a prescriber licensed by the state of Louisiana, his designee, or any member of his staff, while physically present in the state of Louisiana.
  - (4) The board shall have the authority to enter into a contract for the administration of the board's responsibilities pursuant to this Section.
  - (5) Each health profession licensing board that regulates individuals with prescriptive authority in Louisiana shall advise the licensees of the board at least once annually of the opportunity to access this website.
- B. For purposes of this Section:
  - (1) "Pharmaceutical marketer" means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company engages in marketing activities of prescription drugs.
  - (2) "Prescriber" means a physician or any other person authorized to prescribe prescription drugs or any other person on their staff who receives prescription drug marketing materials.
  - (3) "Prescription drug" means a pharmaceutical drug that legally requires a prescription to be dispensed.
  - (4) "Prescription drug marketing" means in-person meetings, mailings, telephonic conversations, video conferencing, and electronic mail activities with prescribers.
  - (5) "Wholesale acquisition cost" means, with respect to a pharmaceutical drug or biological product, the manufacturer's list price for the pharmaceutical drug or biological product to wholesalers or direct purchasers in the United States for the most recent month for which the information is available, as reported in wholesale price guides or other publications of pharmaceutical drug or biological product pricing data, not including prompt pay or other discounts, rebates, or reductions in price.
- C. (1) Implementation of this Section shall be contingent upon the Louisiana Board of Pharmacy's obtaining grant funds from private entities for the development, implementation, operation, and continued maintenance of the drug pricing disclosure website.
  - (2) The board shall actively seek grant funding to implement the provisions of this Section. Within ten months of successful receipt of grant funds sufficient in amount to implement the provisions of this Section, the board shall make the drug pricing disclosure website available to prescribers.
- D. The provisions of this Section shall not apply to veterinarians or pharmaceutical marketers who engage in any form of prescription drug marketing directly to a prescriber, his designee, or any member of his staff regarding prescription drugs manufactured exclusively for nonhuman consumption.

(Section amended by Act 219 of the 2018 Regular Session)

#### [End of Part VI]

#### Part VII. Pharmacy Benefit Managers

(This new Part VII, composed of Sections 1256 through 1258, was added by Act 124 of the 2019 Regular Session, effective July 1, 2020. Subsequent amendments are noted herein.)

## §1256. Louisiana Board of Pharmacy; authority to regulate pharmacy benefit managers

- A. Pursuant to the authority vested in the board in this Chapter and as specifically provided for in the <a href="Pharmacy Benefit Manager Licensing Law, R.S. 40:2861">Pharmacy Benefit Manager Licensing Law, R.S. 40:2861</a> et seq., the board shall create and issue a permit for pharmacy benefit managers as defined in <a href="R.S. 40:2863">R.S. 40:2863</a>.
- B. A pharmacy benefit manager shall be permitted under Part IV of this Chapter if it administers, develops, maintains, performs, or provides one or more pharmacy services in this state or that affects one or more beneficiaries of a pharmacy benefit management plan administered by the pharmacy benefit manager, as set forth in R.S. 40:2868.
- C. (1) A pharmacy benefit manager may file for a hearing conducted before an independent third-party adjudicator with the division of administrative law upon notice from the board that it intends to take adverse or disciplinary action against the pharmacy benefit manager that may result in the suspension or termination of the pharmacy benefit manager's permit. If the pharmacy benefit manager elects to file for a hearing with the division of administrative law, the ruling of the administrative law judge shall be appealable by either the pharmacy benefit manager or the board, whichever party does not prevail.
  - (2) Nothing in this Subsection shall be construed to prevent the pharmacy benefit manager from proceeding with a hearing before the board as provided for in the <u>Administrative Procedure Act</u>, nor shall anything in this Subsection be construed to prevent the board from taking any other action provided by law or rule that would not result in suspension or termination of the pharmacy benefit manager's permit.

(Section amended by Act 536 of the 2022 Regular Session)

## §1257. Pharmacy benefit managers; rules and regulations; reporting requirements; fees

- A. The board shall promulgate rules and regulations in accordance with the <u>Administrative Procedure Act</u> to implement the provisions of this Part and the applicable provisions of the Pharmacy Benefit Manager Licensing Law, <u>R.S. 40:2861</u> *et seq.*
- B. The board may promulgate rules and regulations to specify permit renewal reporting requirements for pharmacy benefit managers.
- C. The board shall charge fees for the issuance of pharmacy benefit manager permits in the amounts authorized by R.S. 37:1184<sup>1</sup>.

(Section amended by Act 202 of the 2020 Regular Session)

## §1258. Pharmacy benefit managers; enforcement

The board shall enforce the provisions of this Part as provided for in this Chapter and R.S. 40:2871.

[End of Part VII]

[End of Chapter 14]

#### *Notes:*

- <sup>1</sup> Subparagraph (c) was added to the definition of 'pharmacy collaborative drug therapy management' during the 2022 Regular Session. The legislature intended to permit the medical board's advisory committee to meet electronically as described in the Open Meeting Law, more specifically at R.S. 42:17.3. During the subsequent 2023 Regular Session, the legislature made substantive revisions to that law, and in the process, repealed Section 17.3. The relevant provisions for electronic meetings of public bodies are now found in Section 17.2. However, the legislature has not yet revised this portion of the pharmacy law to correct that citation.
- <sup>2</sup> Statutory references to R.S. 37:1184 are not hyperlinked to that list of fees since the current list of fees is found in Chapter 1 of the administrative code, more specifically in Section 115.
- <sup>3</sup> Within this instruction for proper substitution procedures for equivalent drug products, the 2001 Regular Session added this reference to the federal rules relative to prescriptions reimbursed by Medicaid. However, that specific Subsection 447.331 is no longer in force. The federal requirement may still be in place within Section 447. The legislature has not yet revised this portion of the pharmacy law to correct that citation.
- <sup>4</sup> This Subsection prevents any provisions of the pharmacy law from restricting any provisions of the nurse practice law, both for registered nurses as well as advanced practice registered nurses. While the provisions for registered nurses are still found in R.S. 37:911, the provisions for advance practice registered nurses are no longer found at R.S. 37:1031 through 1034. The legislature has not yet revised this portion of the pharmacy law to correct that citation.

## **Title 37 – Professions and Occupations**

#### **Chapter 20 – Miscellaneous Provisions Common to Certain Professions**

\* \* \*

## Part III - Medical Prescriptions and Labels

[This new Part III, consisting of Sections 1701 through 1703 was created by Act 327 of the 1926 Regular Session, effective August 1, 1926. Subsequent amendments are noted herein.]

### §1701. Prescription; name of patient and prescription

- A. Each physician, surgeon, optometrist, medical psychologist, and dentist upon writing a prescription shall write the name of the patient and the trade name, or the generic name, or the most commonly used name on the prescription issued.
- B. No druggist, pharmacist, or dispensing physician shall fill any prescription unless the name of the patient and the trade name, or the generic name, or the most commonly used name of the prescription appears on the label, unless otherwise specified by the physician, surgeon, optometrist, medical psychologist, or dentist.

(Section amended by Acts 465 and 672 of the 1976 Regular Session; Act 202 of the 1993 Regular Session; Act 11 of the 2004 Regular Session)

## §1702. Label on container; patient's name

All druggists and pharmacists upon filling any prescription, shall first write or print the name of the patient on the label which label shall be securely attached to the bottle, box, or package containing the medicine or drugs prescribed.

### §1703. Penalty

Whoever violates the provisions of <u>R.S. 37:1701</u> or <u>37:1702</u>, shall be fined not less than five dollars nor more than twenty-five dollars, or imprisoned for not less than ten days nor more than thirty days, or both.

[End of Part III]

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#### Part VII - Health Care Providers

[This new Part VII, consisting of Sections 1744 and 1745, was created by Act 657 of the 1993 Regular Session, effective August 1, 1993. Subsequent amendments are noted herein.]

#### §1744. Disclosure of financial interest by referring healthcare provider

- A. For the purposes of this Section, the following terms have the following meanings:
  - (1) "Board" means Louisiana State Board of Medical Examiners, Louisiana State Board of Dentistry, Louisiana Board of Chiropractic Examiners, Louisiana State Board of Optometry Examiners, Louisiana Physical Therapy Board, Louisiana State Board of Examiners of Psychologists, Louisiana State Board of Nursing, Louisiana Licensed Professional Counselors Board of Examiners, Louisiana State Board of Practical Nurse Examiners, or Louisiana Board of Pharmacy.
  - (2) "Financial interest" means a significant ownership or investment interest established through debt, equity, or other means and held by a healthcare provider or a member of a healthcare provider's immediate family, or any form of direct or indirect remuneration for referral.
  - (3) "Healthcare provider" means a person, partnership, or corporation, licensed by this state to provide health care or professional services as a physician, dentist, chiropractor, podiatrist, optometrist, physical therapist, psychologist, medical psychologist, licensed professional counselor, registered or licensed practical nurse, pharmacist, and any officer, employee, or agent thereof acting in the course and scope of his employment.
- B. No healthcare provider shall make referrals outside the same group practice as that of the referring healthcare provider to any other healthcare provider, licensed healthcare facility, or provider of healthcare goods and services including but not limited to providers of clinical laboratory services, diagnostic services, medicinal suppliers, and therapeutic services when the referring healthcare provider has a financial interest served by such referral, unless in advance of any such referral the referring healthcare provider discloses to the patient, in writing, the existence of such financial interest.

- C. (1) It shall be a violation of this Section for any licensee to enter into any arrangement or scheme, including cross-referral arrangements, if the licensee knows, or should know, that he or she has a principal purpose of ensuring referrals by the licensee to a particular entity, which referral, if made directly by the licensee, would be a violation of this Section.
  - (2) Notwithstanding any other law to the contrary, any healthcare provider who violates the provisions of this Section shall refund all such sums received in payment for the goods and services furnished or rendered without disclosure of financial interest. Such a refund shall be paid to the individual patient, third-party payor, or other entity who made the payment.
  - (3) Each respective board shall promulgate rules and regulations for enforcement of the provisions of this Section. Such rules and regulations shall include sanctions and restitution provisions and shall provide that a violation of this Section constitutes grounds for suspension or revocation of license or other credentials. Each board shall submit to the commissioner of insurance an annual report listing the investigations undertaken pursuant to this Section, including the number of violations and the sanctions imposed, if any.

(Section amended by Act 303 of the 2003 Regular Session; Act 251 of the 2009 Regular Session; Act 206 of the 2018 Regular Session; Act 238 of the 2021 Regular Session)

## §1745. Prohibition on payment for patient referrals

- A. For the purposes of this Section, the following terms have the following meanings:
  - (1) "Board" means Louisiana State Board of Medical Examiners, Louisiana Board of Chiropractic Examiners, Louisiana State Board of Dentistry, Louisiana State Board of Optometry Examiners, Louisiana Physical Therapy Board, Louisiana State Board of Examiners of Psychologists, Louisiana State Board of Nursing, Louisiana Licensed Professional Counselors Board of Examiners, Louisiana State Board of Practical Nurse Examiners, or Louisiana Board of Pharmacy.
  - (2) "Healthcare provider" means a person, partnership, or corporation licensed by the state to provide health care or professional services as a physician, chiropractor, dentist, dental hygienist, podiatrist, optometrist, physical therapist, psychologist, medical psychologist, licensed professional counselor, registered or licensed practical nurse, pharmacist, and any officer, employee, or agent thereof acting in the course and scope of his employment.
- B. No healthcare provider shall offer, make, solicit, or receive payment, directly or indirectly, overtly or covertly, in cash or in-kind, for referring or soliciting patients. Payments representing a return on investment based on a percentage of ownership are not considered a direct or indirect payment for the purposes of this Section.
- C. (1) Each board shall promulgate rules and regulation for the implementation and enforcement of the provisions of Subsection B of this Section in accordance with the <u>Administrative Procedure Act.</u> Such rules and regulations shall include, at a minimum, sanctions and penalty provisions and permissible contracting activities known as "safe harbors."
  - (2) Any activity permissible under the corresponding provisions of Title XVIII of the <u>Social Security Act</u> shall not be a violation of this Section.
  - (3) Violation of Subsection B of this Section by a healthcare provider may constitute grounds for suspension or revocation of license or other credentials by the appropriate board.

(Section amended by Act 782 of the 1999 Regular Session; Act 303 of the 2003 Regular Session; Act 251 of the 2009 Regular Session; Act 206 of the 2018 Regular Session; Act 238 of the 2021 Regular Session)

\* \* \* \*

[End of Part VII]

\* \* \* \*

[End of Chapter 20]

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[End of Title 37]

## Title 40 – Public Health and Safety

## Chapter 4 – Food and Drugs

#### Part I. Adulteration, Substitution, Misbranding, or False Advertising

[This new Part I, consisting of Sections 601 through 642, was created by Act 142 of the 1936 Regular Session, effective August 1, 1936. Subsequent amendments are noted herein.]

## §601. Title

This Part may be cited as the "State Food, Drug, and Cosmetic Law."

## §602. Definition of terms

As used in this Part, unless the context otherwise indicates, the following terms shall have the meaning ascribed to them in this Section:

- (1) "Advertisement" includes all representations of fact or opinion disseminated to the public in any manner or by any means other than by the labeling.
- (2) "Cosmetic" includes all substances and preparations intended for cleansing, altering the appearance of, or promoting the attractiveness of a person. The term includes soaps only when medicinal or curative qualities are claimed by the use thereof.
- (3) "Department" means the Louisiana Department of Health and "secretary" means the secretary thereof.
- (4) "Device" includes all devices intended for use in diagnosis, treatment, or prevention of disease in man or beast, or intended to affect the structure of any function of the body.
- (5) "Drug" includes all substances and preparations recognized in the official compendium, as herein defined. It includes all substances and preparations intended for use in the diagnosis, treatment, or prevention of disease in man or beast, and all substances and preparations, other than food and cosmetics, intended to affect the structure or any function of the body.
- (6) "Food" includes all substances and preparations used for or entering into the composition of food, drink, confectionery, chewing gum, or condiment for man or beast.
- (7) "Label" means the principal display or displays of written, printed, or graphic matter upon any food, drug, device, or cosmetic, or the immediate container thereof, or upon the outside container or wrapper, if any, of the retail package of any food, drug, device, or cosmetic.
- (8) "Labeling" includes all labels and other written, printed, and graphic matter, in any form whatsoever, accompanying any food, drug, device, or cosmetic.
- (9) "Medical opinion" means the opinion, within their respective fields, of the practitioners of any branch of the medical profession, the practice of which is licensed by law in this state.
- (10) "Medical profession" means the legalized profession of the healing art.
- (11) "Official compendium" means the <u>United States Pharmacopeia</u>, <u>Homeopathic Pharmacopeia of the United States</u>, National Formulary, or any supplement of any of them, official at the time any drug, to which the provisions thereof relate, is introduced into commerce.
- (12) "Scientific opinion" means the opinion, within their respective fields, of competent pharmacologists, physiologists, or toxicologists.

(Section amended by Act 786 of the 1978 Regular Session)

## §603. Liability of persons

When construing and enforcing the provisions of this Part, unless otherwise provided, the act or omission of any officer, employee, or agent acting for or employed by any person, within the scope of employment or office, shall in every case be considered the act or omission of such person, as well as that of the officer, employee, or agent. Whenever a corporation or association violates any of the provisions of this Part, unless otherwise provided, the violation shall also be considered a violation by the individual directors, officers or agents of the corporation or association who personally ordered or did any of the acts constituting the violation, in whole or in part.

#### §604. Regulations

The authority to promulgate regulations for the efficient enforcement of this Part is vested in the secretary of the Louisiana Department of Health.

(Section amended by Act 786 of the 1978 Regular Session)

## §605. Examinations, investigations, and hearings conducted by board or agent

The department, or any designated officer or employee thereof, may conduct examinations and investigations for purposes of this Part. Hearings authorized or required by this Part shall be conducted by the department or the officer or employee designated by it for the purpose.

(Section amended by Act 786 of the 1978 Regular Session)

## §606. Court review of regulations and administrative actions; injunctions

On the petition of any interested person, the district courts may:

- (1) Restrain by injunction, temporary or permanent, the enforcement by an officer, representative, or employee of the department of any regulation promulgated by it under the provisions of this Part if it is shown that the regulation is unreasonable, arbitrary, or capricious, or not in accordance with the facts or law, and that the petitioner may suffer substantial damage by reason of its enforcement; and
- (2) Grant appropriate injunctive relief from any act or omission of any officer, representative, or employee of the department in the administration of this Part, if it has been shown that the act or omission is unreasonable, arbitrary or capricious, or not in accordance with the facts or law and that petitioner may suffer substantial damage thereby.

(Section amended by Act 786 of the 1978 Regular Session)

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## §613. Regulations governing issuance and renewal of permit

The department shall make regulations prescribing the time for which the permits are issued and governing the issuance and renewal thereof.

(Section amended by Act 786 of the 1978 Regular Session)

## §614. Suspension of permit; reinstatement

Upon notice to the permittee, the secretary of the department may suspend immediately any permit issued under authority of R.S. 40:612 if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended may apply at any time for its reinstatement. After a prompt hearing and an inspection of the establishment, the department shall immediately reinstate the permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(Section amended by Act 786 of the 1978 Regular Session)

#### §615. Inspection of permittee's establishment; denial of access

Any officer or employee duly designated by the department has access to any factory or establishment, the operator of which holds a permit from the department, for the purpose of ascertaining whether or not the conditions of the permit are being complied with. Denial of access for this inspection is grounds for suspension of the permit until the access is freely given by the operator.

(Section amended by Act 786 of the 1978 Regular Session)

### §616. Adulterated drugs

A drug is considered adulterated if it has been found to be such by any department of the United States government, or:

- (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance.
- (2) If it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health.
- (3) If its container is composed of any poisonous or deleterious substance which may render it injurious to health.
- (4) If it contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with department regulations.
- (5) If its name is recognized in the official compendium, or if it purports to be a drug the name of which is so recognized, and it differs from the standard of strength, quality, or purity as determined by the tests or methods of assay set forth in the official compendium or in the regulations of the department, unless its standard of strength, quality or purity is plainly stated on its label. However, no such department regulation shall be adopted unless tests or methods of assay have not been prescribed in the official compendium or the tests or methods of assay prescribed therein are insufficient and, after due notice by the department of that fact, the official body in charge of he revision of the compendium has not corrected the deficiency.
- (6) If it is not subject to the provisions of Paragraph (5) of this Section and its identity or strength differs from or its or quality falls below that which it purports or is represented to possess.

(7) If any substance has been mixed or packed therewith so as to reduce its quality or strength or substituted wholly or in part therefor.

(Section amended by Act 786 of the 1978 Regular Session)

## §617. Misbranded drugs and devices

- A. A drug or device is considered misbranded if it has been found to be such by any department of the United States government, or:
  - (1) If its labeling is false or misleading in any particular. Any representation concerning any effect of a drug or device is considered false for purposes of this Paragraph if the representation is not supported by demonstrable scientific facts or substantial and reliable medical or scientific opinion.
  - (2) If it is dangerous to health under the conditions of use prescribed in the labeling or advertising thereof.
  - (3) If it is in package form and it does not bear a label containing: (a) the name and place of business of the manufacturer, packer, seller, or distributor, and (b) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. Under Subparagraph (b) of this Paragraph reasonable variations shall be permitted and exemptions as to small packages shall be established by regulations prescribed by the department where compliance with the provisions would impracticable.
  - (3.1) If it is a prescription drug bearing the following words "Caution: Federal law prohibits dispensing without a prescription", and (a) the manufacturer, packager, seller, or distributor of any prescription drug sold, delivered, or offered for sale in the state of Louisiana after January 1, 1976 does not have printed on the label on the immediate container of the drug the name and place of business of the manufacturer and, if different, the name and place of business of the packer or distributor of the final dosage form of the drug; and (b) the manufacturer, packager, seller, or distributor does not have printed on the label on the final dosage form an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. Under Subparagraph (b) of this Paragraph reasonable variations shall be permitted and exemption as to small packages shall be established by regulations prescribed by the department where compliance with the provisions would be impracticable. Wholesalers or jobbers who sell prescription drugs only to retailers or institutions shall be exempt from the provisions of this Paragraph, However, nothing contained in the provisions of this Paragraph shall affect the labeling requirements of a prescription label placed on a container by a pharmacist in the process of dispensing a prescription drug.
  - (3.2) If it contains any quantity of amyl nitrite, isopentyl nitrite or any of their isomers, or butyl nitrite, n-butyl nitrite, isobutyl nitrite, or any of their isomers, and is not labeled "Caution: Louisiana Law prohibits dispensing without a prescription" and its sale is not restricted to the prescription of a physician, except that amyl nitrite may be labeled in accordance with labeling requirements of the Federal Food, Drug and Cosmetic Law.
  - (4) If any information required on the label under any provision of this Part is not prominently placed thereon in such a manner as to be easily seen and in such terms as to be readily understood by purchasers and users of the articles under customary conditions of purchase and use. Due consideration shall be given to the size of the package.
  - (5) If it is for use by man and contains any quantity of any of the following narcotic or hypnotic substances and, except when dispensed on the written order of a member of the medical profession, its label fails to bear the name and quantity or proportion of the substance or derivative and in juxtaposition therewith the statement "Warning May be Habit Forming": Alpha eucaine, barbituric acid, beta eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, sulphomethane, or any substance chemically derived therefrom, except derivatives of coca leaves which do not contain cocaine, ecgonine (or substances from which cocaine or ecgonine may be synthesized or made) or any other narcotic or hypnotic substance designated as habit forming by regulations of the department, unless the derivative is clearly not habit forming.
  - (6) If it is a drug and is not designated solely by a name recognized by an official compendium or if its label has been disapproved by the United States government or the department.
  - (7) If its name is recognized in an official compendium, or if it purports to be a drug the name of which is so recognized, and it is not packaged and labeled as prescribed therein.
  - (8) If it is a drug liable to deterioration and is not packaged in the form or manner required by department regulations for the protection of public health or its label does not bear a statement of those precautions. No such regulation shall be established for any drug recognized in the official compendium until the department shall have informed the appropriate body charged with the revision of the compendium of the need for the packaging or labeling requirements and that body shall have failed within a reasonable time to prescribe those requirements.
  - (9) If it is a drug and its container is so made, formed, or filled as to mislead the purchaser.

(10) If it is a drug and it is an imitation of another drug.

- (11) If it is a drug and it is offered for sale under the name of another drug.
- B. When construing and enforcing the provisions of this Part with respect to labeling and advertisements, the term "antiseptic" has the same meaning as the word "germicide", except, however, in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or for such other use as involves prolonged contact with the body.

(Section amended by Act 524 of the 1975 Regular Session; Acts 140 and 786 of the 1978 Regular Session)

#### §618. Drugs recognized in compendiums

Whenever a drug is recognized in both the <u>United States Pharmacopoeia</u> and the <u>Homeopathic Pharmacopoeia</u> of the <u>United States</u>, it shall be subject to the requirement of the <u>United States Pharmacopoeia</u> for purposes of this Part unless it is labeled and offered for sale as homeopathic drug, in which case it shall be subject to the provisions of the <u>Homeopathic Pharmacopoeia</u> of the <u>United States</u> and not to those of the <u>United States Pharmacopoeia</u>.

## §619. Certain drugs and devices excepted from labeling and packaging provisions

The department shall promulgate regulations exempting from any labeling or packaging requirement of this Part drugs and devices which are, in accordance with the practice of the trade, processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that these drugs and devices are in conformity with the provisions of this Part, upon removal from the processing, labeling, or repacking establishment. (Section amended by Act 786 of the 1978 Regular Session)

## §620. Certification of coal-tar colors for drugs

The department may promulgate regulations for the certification of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only.

(Section amended by Act 786 of the 1978 Regular Session)

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### §625. False advertisement

- A. An advertisement of a food, drug, device, or cosmetic is false if it is false or misleading in any particular regarding the food, drug, device, or cosmetic. Any representation concerning any effect of a drug or device is false under this Subsection if it is not supported by demonstrable scientific facts or substantial and reliable medical or scientific opinion.
- B. Except as provided below, the advertisement of a drug or device representing it to have any therapeutic effect in the treatment of Bright's disease, cancer, tuberculosis, poliomyelitis, venereal disease, heart and vascular diseases, or any other diseases for which no known therapeutic effect has been fully established is false. No advertisement not in violation of Subsection A of this Section shall be considered false under this Subsection, if it is disseminated only to members of the medical and pharmaceutical professions or appears only in the scientific periodicals of these professions, or if it is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of the drugs or devices.
- C. Except as provided in <u>R.S. 40:626</u>, it is unlawful for any person to disseminate false advertisement by any means for the purposes of inducing, directly or indirectly, the purchase of food, drugs, devices, or cosmetics. (Section amended by Act 206 of the 2018 Regular Session)

## §626. Exceptions as to false advertising by agencies

Publishers, radio broadcast licensees, television broadcast licensees, advertising agencies, and other agencies or mediums for dissemination of advertising do not violate the provisions of R.S. 40:625(C) by the dissemination of any false advertisement when the dissemination is caused by the manufacturer, packer, distributor, or seller who resides in Louisiana. However, the manufacturer, packer, distributor, or seller is amenable to prosecution and penalties provided for the violation of that Subsection. No publisher, radio broadcast licensee, television broadcast licensee, advertising agency, or other agency or medium for the dissemination of advertising shall willfully refuse, on reasonable request of an officer or employee duly designated by the department to furnish to the officer or employee the name and post office address of the manufacturer, packer, distributor, or seller, residing in Louisiana, who caused him to disseminate any such advertisement.

(Section amended by Act 786 of the 1978 Regular Session)

## §627. Registration of certain products

A. Except as provided by Subsection E of this Section, the department may require all manufacturers, packers, or proprietors of processed foods, proprietary or patent medicines, prophylactic devices, and cosmetics, in package

- form, to register each separate and distinct product annually with the department and to supply it with a sample of each such product upon request.
- B. The submission of a catalog and specimens of labels shall be required at the time of application for registration of products produced, packaged, and prepared in compliance with the requirements of the <a href="Federal Food, Drug, and Cosmetic Act">Federal Food, Drug, and Cosmetic Act</a>, which will constitute satisfactory compliance for registration of the products. With respect to all other products, submission of a catalog and specimens of labels shall be required at the time of application for registration, but registration will not become effective until examination and approval of the label or product by the department. This approval shall be by written notification to the manufacturer, packer, or processor.
- C. No manufacturer, packer, or proprietor shall sell any product which he has failed to register in conformity with this Section. Such failure also subjects the product to seizure and condemnation as provided by <u>R.S. 40:632</u> through R.S. 40:634.
- D. The department shall assess each manufacturer, packer, or proprietor a penalty of ten dollars for failure to register each separate and distinct product annually as provided in this Section. The penalty assessed shall be in addition to the examination and investigation charges assessed as provided in R.S. 40:628(B). Each failure to register a separate and distinct product shall constitute a separate violation. However, no manufacturer, packer, or proprietor shall be assessed more than one hundred dollars in any calendar year. The department shall promulgate rules and regulations to provide for assessment and collection of the penalty provided in this Subsection.
- E. This Section shall not apply to alcoholic beverages. For purposes of this Section, "alcoholic beverages" has the same meaning as assigned in R.S. 26:2 and 241.

(Section amended by Act 786 of the 1978 Regular Session; Act 10 of the 1983 First Extraordinary Session; Act 344 of the 1985 Regular Session; Act 393 of the 2015 Regular Session)

## §628. Examination and investigation fee; food and drug control fees

- A. All inspection, investigation, and examination fees collected by the department under the provisions of this Part shall be devoted to the expenses of inspections, examinations, and investigations conducted under the authority of this Part and for the maintenance and enforcement of the provisions of this Part.
- B. The department shall charge and collect from the manufacturers, packers, or proprietors of the products referred to in R.S. 40:627 an annual examination and investigation charge of not more than twenty-seven dollars for any one separate and distinct product registered, up to a maximum of two hundred seventy dollars annually from each manufacturer, packer, or proprietor. Manufacturers, packers, or proprietors of soft drinks and nonalcoholic beverages, except nonalcoholic fruit juices, and manufacturers, packers, or proprietors of product offered for sale or sold at retail only in their own establishments are exempt from the payment of examination and investigation charges here authorized.
- C. The department shall charge and collect an annual food and drug control permit fee from manufacturers, packers, and processors of foods, drugs, and cosmetics. The fee shall not apply to any plant required to have a commercial seafood permit pursuant to R.S. 40:31.35. This Section shall not apply to meat packers, meat processors, and meat warehouses, or agricultural commodities or any combination thereof regulated by the state Department of Agriculture and Forestry. The fee shall be for each separate establishment for which a permit is required based on the annual sales of such establishment according to the following schedule:

Annual sales	<u>Annual fee</u>
Under \$500,000	\$ 175.00
\$500,001 - \$1,000,000	475.00
\$1,000,001 - \$2,500,000	775.00
\$2,500,001 - \$5,000,000	1,075.00
Over \$5,000,000	1,375.00

D. The department shall charge and collect an annual food and drug control fee of three hundred dollars from warehouses and distributors of foods, drugs, and cosmetics. The fee shall be for each separate establishment for which a permit is required.

(Section amended by Act 472 of the 1954 Regular Session; Act 786 of the 1978 Regular Session; Act 344 of the 1985 Regular Session; Act 125 of the 2000 First Extraordinary Session)

#### §629. Records of interstate shipment

- A. For the purposes of enforcing the provisions of this Part, carriers engaged in interstate commerce and persons receiving food, drugs, devices, or cosmetics in interstate commerce shall, upon the request in the manner set out below of an officer or employee duly designated by the department, permit the officer or employee to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, and the quantity, shipper, and consignee thereof.
- B. The request provided for in this Section shall be accompanied by a definite statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which it relates.

C. Evidence obtained under this Section shall not be used in criminal prosecution of the person from whom obtained. (Section amended by Act 786 of the 1978 Regular Session)

## §630. Carriers in interstate commerce; excepted from Part

Carriers engaged in interstate commerce are not subject to the provisions of this Part, other than <u>R.S. 40:629</u>, by reason of their receipt, carriage, or delivery of food, drugs, devices, cosmetics, or advertising matter in the usual course of business as carriers.

## §631. Factory inspections

- A. In order to prevent commerce in adulterated or misbranded food, drugs, devices, or cosmetics and to safeguard the public health and prevent deceit upon the purchasing public, officers or employees duly designated by the department, after making reasonable request, may enter any factory, warehouse, or other establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held for storage or shipment in commerce or are held after such shipment, or any vehicle being used to transport food, drugs, devices, or cosmetics in commerce and inspect the factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.
- B. No owner, operator, or custodian of such a place shall refuse this reasonable request, under pain of the penalties provided in this Part.

(Section amended by Act 786 of the 1978 Regular Session)

## §632. Causes for seizure and condemnation of food, drugs, devices, or cosmetics

Any article of food and any drug, device, or cosmetic that is adulterated, misbranded, or unregistered or which has been manufactured, processed, or packed in a factory or establishment, the operator of which did not, at the time of manufacture, processing, or packing, hold an unsuspended valid permit, if so required under <u>R.S. 40:612</u>, is subject to seizure and condemnation by the department or by any officer or employee it designates for that purpose. (Section amended by Act 786 of the 1978 Regular Session)

### §633. Seizure; procedure; prohibition on sale or disposal of article

- A. Whenever a duly authorized officer or employee of the department finds or has probable cause to believe that cause for the seizure of any food, drug, device, or cosmetic, as set out in R.S. 40:632 exists, he shall affix to the article a tag, stamp, or other appropriate marking, giving notice that the article is, or is suspected of being subject to seizure under the provisions of R.S. 40:632 and that is has been detained and seized by the department. He shall also warn all persons not to remove or dispose of the article by sale or otherwise, until permission of the department or of the court of the jurisdiction in which the article is detained or seized is given.
- B. It is unlawful for any person to remove or dispose of the detained or seized article by sale or otherwise without permission of the department or of the court in such cases.

(Section amended by Act 786 of the 1978 Regular Session)

## §634. Condemnation and sale; release

- A. When any article detained or seized under <u>R.S. 40:633</u> has been found by the department to be subject to seizure and condemnation under <u>R.S. 40:632</u>, the department shall petition a court for an order of condemnation or sale, as the court may direct. The proceeds of the sale minus the legal costs and charges shall be paid into the state treasury to the credit of the general fund.
- B. Upon the payment of the costs of the condemnation proceeding and upon the execution and delivery of a surety bond to the effect that the goods shall not be sold or otherwise disposed of contrary to the provisions of this Part, the department or court may order that the goods be delivered to the owner thereof instead of being condemned or sold.
- C. If the department finds that any article seized under the provision of <u>R.S. 40:633</u> was not subject to seizure under that Section, the department or the designated officer or employee shall remove the tag or marking.

(Section amended by Act 786 of the 1978 Regular Session; Act 206 of the 2018 Regular Session)

#### §635. Condemnation or destruction of perishables in certain cases

A. Whenever the department or its duly authorized officer or employee finds in any factory, establishment, structure, or vehicle of transportation any meat, seafood, poultry, vegetables, fruit, or other perishable articles which are unsound or contain any filthy, decomposed, or putrid substance or that may be poisonous or deleterious to health or otherwise unsafe for human consumption, the officer or employee of the department designated by it shall immediately condemn or destroy it or in any other manner render it unconsumable as human food.

B. Nothing in this Title shall be construed to prohibit any duly authorized officer or employee of the department from causing the destruction of any meat, seafood, poultry, vegetables, fruit, or other perishable articles which are of foreign origin and are the subject of a current import ban by an agency of the federal government.

(Section amended by Act 786 of the 1978 Regular Session; Act 195 of the 2021 Regular Session)

## §636. Other prohibited acts

The following acts and the causing thereof are prohibited:

- (1) The introduction or delivery for introduction into commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
- (2) The adulteration, or misbranding, of any food, drug, device, or cosmetic in commerce.
- (3) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof in the original unbroken package for pay or otherwise.
- (4) The forging, counterfeiting, simulating, or falsely representing or, without proper authority, using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of this Part.
- (5) The possession in any place where sales or service is made to the public of any food, drug, device or cosmetic that is adulterated or misbranded.
- (6) The using by any person to his own advantage, or the revealing, other than to the department, its officers or employees, or to the courts when relevant in the trial of any case under this Part, any information acquired under authority of R.S. 40:612 through R.S. 40:615 or R.S. 40:631 concerning any method or process which, as a trade secret, is entitled to protection.

(Section amended by Act 482 of the 1952 Regular Session; Act 786 of the 1978 Regular Session)

### §637. Procedure for reporting violations of Part

- A. Before reporting any violations of this Part to any district attorney for institution of criminal proceedings thereunder, the department may, in accordance with regulations prescribed by it, afford appropriate notice and opportunity for hearing to interested persons upon the question of such violations. The report to the district attorney when such hearings are held shall be accompanied by findings of the appropriate officers and employees.
- B. The department need not report for prosecution minor violations of this Part when the purposes of the Part can best be accomplished by a suitable written notice or warning.

(Section amended by Act 786 of the 1978 Regular Session; Act 346 of the 1985 Regular Session)

## §638. Duties of district attorney

Each district attorney to whom the department reports any violation for institution of criminal or injunction proceedings under this Part, or to whom any health, food, or drug officer of the state or political subdivision thereof, presents evidence satisfactory to the district attorney, of any such violation, shall institute appropriate proceedings in the proper court without delay.

(Section amended by Act 786 of the 1978 Regular Session)

#### §639. Penalties

Except as provided in <u>R.S. 40:971.3</u>, whoever violates any provision of this Part shall be fined, for the first offense, not more than one thousand dollars or imprisoned for not more than one year, or both. For the second or subsequent offense, he shall be fined not more than three thousand dollars or imprisoned for not more than two years, or both. But any person who violates the provisions of <u>R.S. 40:625(C)</u> shall only be fined not more than one thousand dollars for each violation if the violation does not involve gross deception or imminent danger to health, and is established by opinion evidence only.

(Section amended by Act 108 of the 2017 Regular Session)

## §640. Dealers excepted from penalty in certain cases

No dealer is subject to the penalties of R.S. 40:639:

- (1) For having received any article of food, drug, device, or cosmetic and in good faith sold it as received unless he refuses to furnish on request of an officer or employee duly designated by the department the name and address of the person from whom he purchased or received the article and all documents pertaining to the delivery of the article to him; or
- (2) If he established a guaranty or undertaking signed by the person residing in Louisiana from whom he received in good faith the article of food, drug, device, or cosmetic, or advertising copy thereof to the effect that the designated article is not adulterated or misbranded within the meaning of this Part and that the copy is not false. To afford protection, this guaranty or undertaking shall contain the name and address of the person furnishing it.

This person shall be amendable to the prosecution and penalties which would attach in due course to the dealer under the provisions of this Part.

(Section amended by Act 316 of the 1950 Regular Session; Act 786 of the 1978 Regular Session)

## §641. Injunction proceedings

- A. In order to avoid multiplicity of criminal prosecutions, the district courts may, for cause, restrain any person by temporary or permanent injunction from the repetitious introduction or causing to be introduced into commerce of any adulterated, misbranded, or unregistered food, drug, device, or cosmetic; or from the dissemination or causing to be disseminated of a false advertisement by any means for the purpose of inducing, directly or indirectly, the purchase of food, drugs, devices, or cosmetics in commerce.
- B. In these injunction proceedings it is not necessary to show an intent on the part of the person enjoined to continue the offense.
- C. Violation of any injunction issued pursuant to this Section shall be summarily tried and punished by the court as a contempt. The contempt proceedings may be instituted by order of the court or by the filing of an information by the district attorney and process of the court for the arrest of the violator may be served at any place in the state.
- D. No person violates any injunction issued pursuant to this Section by reason of the dissemination, subsequent to the injunction, of the false advertisement which was the basis of the injunction, if the dissemination was beyond the control of the person.

(Section amended by Act 206 of the 2018 Regular Session)

[End of Part I]

## Part X. Uniform Controlled Dangerous Substances Law

[The Uniform Controlled Dangerous Substances Law was created by Act 634 of the 1972 Regular Session, effective August 1, 1972. Subsequent amendments are noted herein.]

#### §961. Definitions

As used in this Part, the following terms have the meaning ascribed to them in this Section unless the context clearly indicates otherwise:

- (1) "Addict" means a drug dependent person who habitually uses any narcotic drugs as to have lost the power of self-control with reference to his use of said drugs.
- (2) "Administer" means to deliver under the auspices of a registered practitioner a controlled dangerous substance to the ultimate user or human research subject by injection, or for inhalation, or ingestion, or by any other means except where otherwise provided by law.
- (3) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser, but does not include a common or contract carrier, public warehouseman, or employee thereof.
- (4) "Aggregate" means the gross weight of an exhibit of evidence.
- (5) "Apothecary" means a licensed pharmacist as defined by the laws of this state, and where the context so requires, the owner of the store or other place of business where narcotic drugs are compounded or dispensed by a licensed pharmacist; but nothing in this Part shall be construed as conferring on a person who is not registered nor licensed as a pharmacist any authority, right or privilege that is not granted to him by the pharmacy laws of this state.
- (6) "Cannabis" includes all parts of plants of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of such plant, and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin, but shall not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake or the sterilized seed of such plant which is incapable of germination.
- (7) "Control" means to add a drug or other substance, or immediate precursor, to a schedule under <u>R.S. 40:964</u>, whether by transfer from another schedule or otherwise.
- (8) "Controlled dangerous substance" means any substance defined, enumerated, or included in federal or state statute or regulations, 21 CFR §1308.11 through 1308.15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled dangerous substance by amendment or supplementation of such regulations or statute. The term shall not include distilled spirits, wine, malt beverages, or tobacco.
- (9) "Controlled substance analogue" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled dangerous substance in Schedule I or II of R.S. 40:964; which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled dangerous substance in Schedule I or II; or with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled dangerous substance in Schedule I or II. Such term shall not include any substance for which there is an approved new drug application; with respect to a particular person any substance, if an exemption is in effect for investigational use, for that person, under the federal Food, Drug, and Cosmetic Act (21 U.S.C.A. §355) to the extent conduct with respect to such substance is pursuant to such exemption; or any substance to the extent not intended for human consumption before an exception takes effect with respect to that substance.
- (10) "Counterfeit controlled dangerous substance" means a controlled dangerous substance which, without authorization, bears the trademark, trade name or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who in fact manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser.
- (11) "Deliver" or "delivery" means the transfer of a controlled dangerous substance whether or not there exists an agency relationship.
- (12) "Dentist" means a person licensed and authorized by law to practice dentistry in this state.
- (13) "Depressant" means a drug which contains any quantity of barbituric acid or any of the salts of barbituric acid; or any derivatives of barbituric acid; or any substance listed in Schedule I(D), Schedule II(D), or Schedule III(B) of R.S. 40:964, or which has been designated by the secretary of the Louisiana Department of Health as habit forming because of its depressant effect on the central nervous system.
- (14) "Dispense" means to deliver a controlled dangerous substance to the ultimate user or human research subject by or pursuant to the lawful order of a practitioner, including the packaging, labeling, or compounding necessary to prepare the substance for such delivery.

- (15) "Distribute" means to deliver a controlled dangerous substance whether by physical delivery, administering, subterfuge, furnishing a prescription, or by filling, packaging, labeling, or compounding the substance pursuant to the lawful order of a practitioner.
- (16) "Distributor" means a person who delivers a controlled dangerous substance as herein defined.
- (17) "Drug" means:
  - (a) articles recognized in the official <u>United States Pharmacopeia</u>, official <u>Homeopathic Pharmacopeia of the United States</u>, or official <u>National Formulary</u>, or any supplement to any of them.
  - (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.
  - (c) articles other than food intended to affect the structure of any function of the body of man or other animals.
  - (d) articles intended for use as a component of any article specified in Subparagraph (a), (b), or (c) of this Paragraph, but does not include devices or their components, parts or accessories.
- (18) "Drug dependent person" means a person who is using a controlled dangerous substance and who is in a state of psychic or physical dependence, or both, arising from administration of that controlled dangerous substance on a continuous basis. Drug dependence is characterized by behavioral and other responses which include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects, or to avoid the discomfort of its absence.
- (19) "Drug Enforcement Administration" means the Drug Enforcement Administration, United States Department of Justice or its successor.
- (20) "Hallucinogen" means a drug which contains any quantity of LSD (lysergic acid diethylamide), its isomers, salts, salts of isomers, or any quantity of a substance listed in Schedule I(C) of R.S. 40:964, or any substance which the secretary of the Louisiana Department of Health after investigation has found to have, and by regulation designates as having, a potential for abuse because of its depressant or stimulant effect on the central nervous system, or hallucinogenic effect.
- (21) "Imitation controlled dangerous substance" means a noncontrolled substance which by appearance or operation, including color, shape, size, markings, or packaging, or by representations made, or by its pharmacological effect, would lead a reasonable person to believe that the substance is a controlled dangerous substance.
- (22) "Immediate precursor" means a substance which the secretary of the Louisiana Department of Health has found to be, and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled dangerous substance, the control of which is necessary to prevent, curtail, or limit such manufacture.
- (23) "Industrial hemp" means the plant Cannabis sativa and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, and salts of isomers, whether growing or not, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis and cultivated and processed in accordance with the U.S. <u>Agriculture Improvement Act of 2018</u>, or the plan submitted by the Department of Agriculture and Forestry that is in compliance with the U.S. Department of Agriculture rules.
- (24) "Isomers" refers to optical isomers and/or stereoisomers and mixtures thereof, unless specifically excepted in this Part. Optical isomers or stereoisomers are molecules which differ from each other only in the way the constituent atoms are oriented in space.
- (25) "Legend drug" means any drug or drug product bearing on the label of the manufacturer or distributor, as required by the federal Food and Drug Administration, the statement "Caution: Federal law prohibits dispensing without prescription."
- (26) "Manufacture" means the production, preparation, propagation, compounding, or processing of a controlled dangerous substance, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Manufacturer includes any person who packages, repackages, or labels any container of any controlled dangerous substance, except practitioners who dispense or compound prescription orders for delivery to the ultimate consumer.
- (27) (a) "Marijuana" means all parts of plants of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin.
  - (b) "Marijuana" shall not include the following:
    - (i) Industrial hemp that is in the possession, custody, or control of a person who holds a license issued by the Department of Agriculture and Forestry, or is cultivated and processed in accordance with the U.S. Agriculture Improvement Act of 2018.
    - (ii) The mature stalks of plants of the genus Cannabis, fiber produced from such stalks, oil, or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.

- (iii) Cannabinoids when contained in a drug product approved by the United States Food and Drug Administration.
- (28) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
  - (a) opium, coca leaves, and opiates.
  - (b) a compound, manufacture, salt, derivatives, or preparation of opium, coca leaves, or opiates.
  - (c) a substance and any compound, manufacture, salt, derivative, or preparation thereof which is chemically identical with any of the substances referred to in Subparagraphs (a) and (b) of this Paragraph, except that the words "narcotic drug" as used in this Part shall not include decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine.
- (29) "Nitrogen-heterocyclic analog" means a nitrogen-heterocyclic analog of a synthetic cannabinoid which has a single carbon atom in a cyclic structure of a compound replaced by a nitrogen atom.
- (30) "Opiate" means any dangerous substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under R.S. 40:963, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.
- (31) "Opium poppy" means the plant of the species Papaver somniferum, except the seeds thereof.
- (32) "Person" includes any institution whether public or private, hospitals or clinics operated by the state or any of its political subdivisions, and any corporation, association, partnership, or one or more individuals.
- (33) "Physical dependence" means a physiologic state of neuroadaptation which is characterized by the emergence of a withdrawal syndrome if drug use is stopped or decreased abruptly, or if an antagonist is administered. Physical dependence is an expected result of opioid use. Physical dependence, by itself, does not equate with addiction.
- (34) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.
- (35) "Practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled dangerous substance in the course of professional practice or research in this state.
- (36) "Prescribe" means to issue a written request or order for a controlled dangerous substance by a person licensed under this Part for a legitimate medical purpose. The act of prescribing must be in good faith and in the usual course of the licensee's professional practice.
- (37) "Prescription" means a written request for a drug or therapeutic aid issued by a licensed physician, dentist, veterinarian, osteopath, or podiatrist for a legitimate medical purpose, for the purpose of correcting a physical, mental, or bodily ailment, and acting in good faith in the usual course of his professional practice.
- (38) "Production" means the manufacture, planting, cultivation, growing, or harvesting of a controlled dangerous substance.
- (39) "Secretary" means the secretary of the Louisiana Department of Health, or his successor.
- (40) "State" means the state of Louisiana.
- (41) "Stimulant" means a drug which contains a quantity of amphetamine or any of its isomers; any salt of amphetamine or any salt of amphetamine; or any substance listed in Schedules II(C) or Schedule III(A) of R.S. 40:964, or any substance which the secretary of the Louisiana Department of Health after investigation, has found to be and by regulation designated as habit forming because of its stimulant effect on the central nervous system.
- (42) "Substance abuse" or "addiction" means a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological, or physical consequences, the continued use of which results in a decreased quality of life. The development of controlled dangerous substance tolerance or physical dependence does not equate with substance abuse or addiction.
- (43) "Third-party logistics provider" means a person who provides or coordinates warehousing, facilitation of delivery, or other logistic services for a legend drug or legend device in interstate and intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not take ownership of the legend drug or legend device nor have responsibility to direct the sale or disposition of the legend drug or legend device.
- (44) "Tolerance" means the physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce the same effect or a reduced effect is observed with a constant dose. Controlled dangerous substance tolerance refers to the need to increase the dose of the drug to achieve the same level of analgesia. Controlled dangerous substance tolerance may or may not be evident during controlled dangerous substance treatment.
- (45) "Ultimate user" means a person who lawfully possesses a controlled dangerous substance for his own use or for the use of a member of his household or for administration to an animal owned by him or a member of his

household.

(Section amended by Act 207 of the 1973 Regular Session; Act 700 of the 1975 Regular Session; Act 649 of the 1977 Regular Session; Act 786 of the 1978 Regular Session; Act 1059 of the 1992 Regular Session; Act 154 of the 1993 Regular Session; Act 34 of the 1994 Regular Session; Act 761 of the 2003 Regular Session; Act 698 of the 2004 Regular Session; Act 8 of the 2013 Regular Session; Act 100 of the 2017 Regular Session; Acts 186 and 677 of the 2018 Regular Session; Act 354 of the 2019 Regular Session; Act 96 of the 2021 Regular Session)

#### §961.1. Industrial hemp exemption

Notwithstanding the definitions provided for in <u>R.S. 40:961(6)</u> and (27), the provisions of the <u>Uniform Controlled Dangerous Substances Law</u> shall not apply to industrial hemp or consumable hemp products as provided for in <u>Parts V</u> and <u>VI</u> of Chapter 10-A of Title 3 of the Louisiana Revised Statutes of 1950.

(Section added by Act 164 of the 2019 Regular Session; amended by Act 498 of the 2022 Regular Session)

## §962. Authority to control

- A. All controlled dangerous substances listed in <u>R.S. 40:964</u> are hereby controlled.
- B. The secretary shall add a substance as a controlled dangerous substance if it is classified as a controlled dangerous substance by the Drug Enforcement Administration of the United States government.
- C. The secretary may by rule add to the schedules provided in R.S. 40:964 any drug or other substance if he finds that such drug or other substance has a high potential for abuse, and after such a finding by the secretary, the drug shall be added in the appropriate schedule under the criteria provided under R.S. 40:963. In making a finding that a drug or other substance has a high potential for abuse, the secretary shall consider the following factors with respect to each drug or other substance proposed to be controlled:
  - (1) Its actual or relative potential for abuse.
  - (2) Scientific evidence of its pharmacological effect, if known.
  - (3) State of current scientific knowledge regarding the substance.
  - (4) Its history and current pattern of abuse.
  - (5) Its scope, duration and significance of abuse.
  - (6) What, if any, risk there is to public health.
  - (7) Its psychic or physiological dependence liability.
  - (8) Whether the substance is an immediate precursor of a substance already controlled by this Section.
- D. In an adjudication the secretary may transfer a controlled substance from one schedule to another schedule upon the basis of a finding that the characteristics of the controlled drug or substances are such that under the criteria in R.S. 40:963 the controlled substance should be transferred or that a transfer of any substance listed under R.S. 40:964 from one schedule to another schedule should be made in order to conform with the schedule in which the drug is placed by the Drug Enforcement Administration of the United States government.
- E. If the secretary designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.
- F. The secretary shall exclude any nonnarcotic substance from a schedule if the substance may, under the federal Food, Drug, and Cosmetic Act and the law of this state, be lawfully sold over the counter without a prescription.
- G. The reclassification of any controlled dangerous substance or its transfer from one schedule to another by the secretary or the state health officer shall not affect the penalties provided by this Part.
- H. If the scheduling of a substance in Schedule I is necessary to avoid an imminent peril to the public health, safety, or welfare, the secretary may adopt an emergency rule adding the substance to Schedule I pursuant to R.S. 49:962. In determining whether the substances pose an imminent peril to the public health, safety, or welfare, the secretary shall consider the factors set forth in Paragraphs C(4), (5), and (6) of this Section.
- I. The secretary may by rule delete any drug or other substance from the schedules provided in <u>R.S. 40:964</u> if the drug or other substance is no longer classified as a controlled dangerous substance by the United States Drug Enforcement Administration.

(Section amended by Act 649 of the 1977 Regular Session; Act 717 of the 1978 Regular Session; Act 34 of the 1994 Third Extraordinary Session; Act 206 of the 2108 Regular Session; Acts 96 and 211 of the 2021 Regular Session)

#### §962.1. Ephedrine products

- A. Except as provided in Subsection B of this Section, any product that contains any quantity of ephedrine, a salt of ephedrine, an optical isomer of ephedrine only upon the prescription of a duly licensed practitioner authorized by the laws of the state to prescribe prescription drugs.
- B. The following products containing ephedrine shall be exempt from the provisions of Subsection A of this Section provided that such product may lawfully be sold over the counter without a prescription under the federal <u>Food</u>, <u>Drug</u>, <u>and Cosmetic Act</u>, is labeled and marketed in a manner consistent with the pertinent OTC Tentative Final or

Final Monograph, and is manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse:

- (1) Solid oral dosage forms (including soft gelatin caplets) that combine active ingredients in the following ranges for each dosage unit:
  - (a) Theophylline (100-130 mg), Ephedrine (12.56-24 mg).
  - (b) Theophylline (60-100 mg), Ephedrine (12.5-24 mg), Guaifenesin (200-400 mg).
  - (c) Ephedrine (12.5-25 mg), Guaifenesin (200-400 mg).
  - (d) Phenobarbital (not greater than 8 mg) in combination with ingredients of Subparagraph (a) or (b) of this Paragraph.
- (2) Liquid oral dosage forms that combine active ingredients in the following ranges for each (5 ml) dose:
  - (a) Theophylline (not greater than 45 mg), Ephedrine (not greater than 36 mg), Guaifenesin (not greater than 100 mg), Phenobarbital (not greater than 12 mg).
  - (b) Phenylephrine (not greater than 5 mg), Ephedrine (not greater than 5 mg), chlorpheniramine (not greater than 2 mg), dextromethorphan (not greater than 10 mg), ammonium C1 (not greater than 40 mg), ipecae fluid extract (not greater than 0.005 ml).
- (3) Anorectal preparations containing less than five percent ephedrine.
- (4) Any liquid compound, mixture, or preparation containing one-half percent or less of ephedrine.
- C. The marketing, advertising, or labeling of any nonprescription product containing ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine for the indication of stimulation, mental alertness, weight loss, appetite control, or energy is prohibited. The Louisiana Department of Health, office of public health is authorized to adopt rules and regulations in accordance with the <u>Administrative Procedure Act</u> to exempt other nonprescription products from the prohibition contained herein. Such rules and regulations shall require a distributor or manufacturer seeking an exemption from the prohibition contained herein to clearly demonstrate that the nonprescription product is intended for use for a valid medicinal purpose and that the marketing of that product does not encourage, promote, or abet the abuse or misuse of ephedrine. In addition, such rules and regulations shall include the following factors for purposes of determining whether or not such an exemption should be granted:
  - (1) The packaging of the product.
  - (2) The name and labeling of the product.
  - (3) The manner of distribution, advertising, and promotion of the product.
  - (4) Verbal representations made concerning the product.
  - (5) The duration, scope, and significance of abuse or misuse of the particular product.
- D. Whoever violates any provision of this Section shall be fined not more than one thousand dollars, or imprisoned for not more than six months, or both.
- E. Notwithstanding any provision of law to the contrary, unless listed in another schedule, any product that contains any quantity of ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine is a Schedule V controlled dangerous substance and shall be dispensed, sold, or distributed only in accordance with the provisions of R.S. 40:1049.1 et seq. Such products shall be exempt from the reporting for Schedule V drugs as provided for in R.S. 40:1001 et seq.

(Section added by Act 1253 of the 1995 Regular Session; amended by Act 314 of the 2009 Regular Session; Act 206 of the 2018 Regular Session)

# §962.1.1. Possession of twelve grams or more of ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers

- A. (1) It is unlawful for any person to possess twelve grams or more of ephedrine, pseudoephedrine, or phenyl-propanolamine or their salts, optical isomers, or salts of optical isomers.
  - (2) It is unlawful for any person to possess ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, or salts of optical isomers in powder form unless the weight of the ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers or salts of optical isomers is less than twelve grams and the powder is in the manufacturer's original packaging and may be lawfully sold over the counter without a prescription under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq.
- B. The provisions of this Section shall not apply to any of the following:
  - (1) Any person possessing a valid prescription for ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers.
  - (2) Any licensed manufacturer, wholesaler, or distributor who sells, transfers, or otherwise furnishes ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers to any licensed practitioner operating within the course and scope of that profession.
  - (3) Any licensed pharmacist or other authorized person who sells or furnishes ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers in the course of their

- professional practice, pursuant to the prescription of any licensed practitioner.
- (4) Any licensed practitioner who administers or furnishes ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers in the course of their professional practice.
- (5) Any person in possession of ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers in his residence under circumstances that are consistent with typical medicinal or household use. Factors that the court may consider in determining whether the circumstances of the possession are consistent with typical medicinal or household use, include but are not limited to storage location, purchase date, expiration date, possession of the products in a variety of strengths, brands, types, or purposes and the health conditions of persons in the residence.
- (6) Any manufacturer, wholesaler, distributor, or retail business which sells, transfers, or otherwise furnishes products to customers for medicinal purposes, which products contain ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers, while acting within the scope and course of that business.
- C. The provisions of this Section shall not apply to any pediatric products primarily intended for administration, according to label instructions, to children under twelve years of age provided that:
  - (1) For any solid dosage form, the individual dosage unit, according to label instructions, does not exceed fifteen milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine.
  - (2) For any liquid dosage form, the recommended dosage units, according to label instructions, does not exceed fifteen milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine per five milliliters of the liquid product.
  - (3) For any liquid dosage form intended for administration to children under two years of age, the recommended dosage does not exceed two milliliters and the total package content is not more than one fluid ounce.
- D. (Subsection D repealed by Act 314 of the 2009 Regular Session)
- E. Whoever violates any provision of this Section shall be fined not more than two thousand dollars or imprisoned, with or without hard labor, for not more than two years, or both.
- F. Notwithstanding any provision of law to the contrary, unless listed in another schedule, any product that contains any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers is a Schedule V controlled dangerous substance and shall be dispensed, sold, or distributed only in accordance with the provisions of R.S. 40:1049.1 et seq. Such products shall be exempt from the reporting for Schedule V drugs as provided for in R.S. 40:1001 et seq.

(Section added by Act 1000 of the 2003 Regular Session; amended by Act 656 of the 2004 Regular Session; Act 314 of the 2009 Regular Session; Act 206 of the 2018 Regular Session)

# §962.1.2. Restriction on the sale and purchase of nonprescription products containing dextromethorphan, its salts or optical isomers, and salts of optical isomers

- A. (1) It shall be unlawful to sell a nonprescription material, compound, mixture, or preparation containing any detectable quantity of dextromethorphan, its salts or optical isomers, or salts of optical isomers to any person under the age of eighteen.
  - (2) It shall be unlawful for any person under the age of eighteen to purchase or attempt to purchase a nonprescription material, compound, mixture, or preparation containing any detectable quantity of dextromethorphan, its salts or optical isomers, or salts of optical isomers.
- B. (1) A nonprescription material, compound, mixture, or preparation containing any detectable quantity of dextromethorphan, its salts or optical isomers, or salts of optical isomers shall not be sold unless the purchaser submits a valid, current form of photo identification issued by the state of Louisiana, another state, or the government of the United States, including but not limited to a driver's license, military identification card, state identification card, or passport.
  - (2) Each form of identification shall on its face establish the age of the person as eighteen years or older, and there must be no reason to doubt the authenticity or correctness of the identification. No form of identification shall be accepted as proof of age if it is expired, defaced, mutilated, or altered. If the state identification card or lawful identification submitted is a duplicate, the person shall submit additional information which contains the name, date of birth, and photograph of the person.
- C. The provisions of this Section shall not apply to a compound, mixture, or preparation containing any detectable quantity of dextromethorphan which is dispensed pursuant to a valid prescription from a licensed practitioner with prescriptive authority.
- D. (1) A person who violates the provisions of this Section by selling a nonprescription compound, mixture, or preparation containing any detectable quantity of dextromethorphan, its salts or optical isomers, or salts of optical isomers shall be fined not more than fifty dollars for the first violation. The penalties for subsequent violations shall include a fine of not more than one hundred dollars for the second violation and a fine of not

- more than one hundred fifty dollars for the third and any subsequent violation.
- (2) A person who violates the provisions of this Section by purchasing or attempting to purchase a nonprescription compound, mixture, or preparation containing any detectable quantity of dextromethorphan, its salts or optical isomers, or salts of optical isomers shall be fined not more than fifty dollars for a first violation and not more than two hundred dollars for a second or subsequent violation.
- E. The legislature hereby recognizes the need for uniformity in the sales of nonprescription compounds, mixtures, or preparations containing any detectable quantity of dextromethorphan, its salts or optical isomers, and salts of optical isomers. Therefore, the provisions of this Section shall supersede and preempt any rule, regulation, code, statute, or ordinance of any political subdivision or other unit of local government that attempts to regulate the sale or purchase of nonprescription compounds, mixtures, or preparations containing any detectable quantity of dextromethorphan, its salts or optical isomers, and salts of optical isomers.

(Section added by Act 176 of the 2014 Regular Session)

## §962.2. Abortion-inducing drugs; restrictions of sales; exceptions; penalties

- A. Except as provided in <u>R.S. 40:1061.11</u>, no abortion-inducing drugs may be sold, prescribed, dispensed, distributed, or delivered in this state in violation of this Section.
- B. Notwithstanding any other provision of law to the contrary, delivery to a person in Louisiana by mail-order, courier, or as a result of a sale made via the internet in violation of this Section is strictly prohibited.
- C. (1) The Louisiana Department of Health may promulgate rules pursuant to the <u>Administrative Procedure Act</u> to provide for exemptions from this Section for products using an abortion-inducing drug which are distributed for other purposes that do not include causing an abortion.
  - (2) A physician or other healthcare provider who is licensed to prescribe medications or drugs that are subject to the provisions of Paragraph (1) of this Subsection shall write a diagnosis or a diagnosis code on the prescription that clearly indicates that the prescription is not intended to cause an abortion in violation of this Section.
- D. (1) Whoever violates any provisions of this Section shall be fined not more than one thousand dollars or imprisoned for not more than six months, or both.
  - (2) Each instance of a sale or distribution of an abortion-inducing drug shall be considered a separate offense for purposes of the penalties provided in Paragraph (1) of this Subsection.
- E. Possessing for her own consumption or consuming an abortion-inducing drug by a pregnant woman in violation of this Section shall not subject the pregnant woman to the criminal consequences.
- F. An act by a licensed pharmacist or pharmacy related to filling a prescription for a drug, medicine, or other substance prescribed for a bona fide medical reason shall not subject the pharmacist or the pharmacy to the criminal consequences of this Section. A diagnosis or a diagnosis code shall be written on the prescription by the prescriber indicating that the drug, medicine, or other substance is intended for a purpose other than to cause an abortion in violation of this Section.

(Section added by Act 548 of the 2022 Regular Session)

#### §963. Schedules of controlled dangerous substances

There are established five schedules of controlled substances, to be known as Schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in <u>R.S. 40:964</u>. In determining that a substance is to be added to these schedules, the secretary shall find the following:

- A. As to Schedule I:
  - (1) The drug or other substance has a high potential for abuse.
  - (2) The drug or other substance has no currently accepted medical use in treatment in the United States, and
  - (3) There is a lack of accepted safety for use of the drug or other substance under medical supervision.
- B. As to Schedule II:
  - (1) The drug or other substance has a high potential for abuse.
  - (2) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions, and
  - (3) Abuse of the drug or other substances may lead to severe psychological or physical dependence.
- C. As to Schedule III:
  - (1) The drug or other substance has a potential for abuse less than the drugs or other substances listed in Schedules I and II.
  - (2) The drug or other substance has a currently accepted medical use in treatment in the United States, and
  - (3) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.
- D. As to Schedule IV:
  - (1) The drug or other substance has a low potential for abuse relative to the drugs or other substances listed in

- Schedule III.
- (2) The drug or other substance has a currently accepted medical use in treatment in the United States, and
- (3) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances listed in Schedule III.
- E. As to Schedule V:
  - (1) The drug or other substance has a low potential for abuse relative to the drugs or other substances listed in Schedule IV.
  - (2) The drug or other substance has a currently accepted medical use in treatment in the United States, and
  - (3) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances listed in Schedule IV.

(Section amended by Act 649 of the 1977 Regular Session; Act 206 of the 2018 Regular Session)

### §964. Composition of schedules

Schedules I, II, III, IV, and V shall, unless and until added to pursuant to <u>R.S. 40:962</u>, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

#### Schedule I

- A. Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, or salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, or salts is possible within the specific chemical designation:
  - \*(1) Acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-N-phenylacetamide)
  - \* (2) Acetylmethadol
  - \* (3) Acrylfentanyl (N-[1-(2-phenylethyl)piperidin-4-yl]-N-phenylacrylamide)
  - \* (4) Allylprodine
  - \* (5) Alphacetylmethadol (except levo-alphacetylmethadol, also known as levomethadyl acetate, or LAAM)
  - \* (6) Alphameprodine
  - \* (7) Alphamethadol
  - \* (8) Alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine)
  - \* (9) Alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide)
  - \* (10) Alpha-methyl butyryl fentanyl (2-methyl-N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide)
  - \* (11) Benzethidine
  - \* (12) Betacetylmethadol
  - \* (13) Beta-hydroxy-3-methylfentanyl (N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenyl-propanamide)
  - \* (14) Beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropanamide)
  - \* (15) Beta-hydroxythiofentanyl (N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide)
  - \* (16) Betameprodine
  - \* (17) Betamethadol
  - \* (18) beta-methylfentanyl (N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)propanamide)
  - \* (19) beta-phenylfentanyl (N-(1-phenethylpiperidin-4-yl)-N,3-diphenylpropanamide)
  - \* (20) Betaprodine
  - \* (21) Brorphine (1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2H-benzimidazol-2-one)
  - \* (22) Butonitazene (N,N-diethyl-2-[(4-butoxyphenyl)methyl)]-5-nitro-1H-benzimidazole-1-ethanamine)
  - \* (23) Butyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide)
  - \* (24) Clonitazene
  - \* (25) Crotonyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide)
  - \* (26) Cyclopentyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide)
  - \* (27) Cyclopropyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide)
  - \* (28) Dextromoramide
  - \* (29) Diampromide
  - \* (30) 3,4-Dichloro-N-[[1-(dimethylamino)cyclohexyl]methyl]-benzamide (AH-7921)
  - \* (31) Diethylthiambutene
  - \* (32) Difenoxin
  - \* (33) Dimenoxadol
  - \* (34) Dimepheptanol
  - \* (35) 2,5-Dimethoxyfentanyl (N-(1-(2,5-dimethoxyphenethyl)piperidine-4-yl)-N-phenylpropionamide)
  - \* (36) Dimethylthiambutene
  - \* (37) Dioxaphetyl butyrate

- \* (38) Dipipanone
- \* (39) Ethylmethylthiambutene
- \* (40) Etodesnitazene (N,N-diethyl-2-[(4-ethoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine)
- \* (41) Etonitazene
- \* (42) Etoxeridine
- \* (43) Fentanyl carbamate (ethyl(1-phenethylpiperidin-4-yl)(phenyl)carbamate)
- \* (44) Flunitazene (N,N-diethyl-2-[4-fluorophenyl)methyl]-5-nitro-1H-benzimidazole-1-ethanamine)
- \* (45) 4-Fluoroisobutyryl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide)
- \* (46) 2-fluoro-orthofluorofentanyl (N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propanamide)
- \* (47) Furanylfentanyl (N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide)
- \* (48) Furethidine
- \* (49) Hydroxypethidine
- \* (50) Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide)
- \* (51) Isotonitazene (N,N-diethyl-2-[(4-isopropoxyphenyl)methyl]-5-nitro-1H-benzimidazole-1-ethanamine)
- \* (52) Ketobemidone
- \* (53) Levomoramide
- \* (54) Levophenacylmorphan
- \* (55) Methoxyacetylfentanyl (2-methoxy-N-[1-(2-phenylethyl)piperidin-4-yl]-N-phenylacetamide)
- \* (56) 4-methylacetylfentanyl (N-(1-(4-methylphenethyl)piperidin-4-yl)-N-phenylacetamide)
- \* (57) 3-methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide)
- \* (58) 3-methylthiofentanyl (N-[3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide)
- \* (59) 2-Methyl AP-237 (1-(2-methyl-4-(3-phenylprop-2-en-1-yl)piperazin-1-yl)butan-1-one)
- \* (60) Metodesnitazene (N,N-diethyl-2-[(4-methoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine)
- \* (61) Metonitazene (N,N-diethyl-2-[(4-methoxyphenyl)methyl]-5-nitro-1H-benzimidazole-1-ethanamine)
- \* (62) Morpheridine
- \* (63) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine)
- \* (64) MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine)
- \* (65) (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide) [Acetyl fentanyl]
- \* (66) N-pyrrolidino etonitazene (2-[(4-ethoxyphenyl)methyl]-5-nitro-1-[2-(pyrrolidino-1-yl)ethyl]-1H-benzimidazole)
- \* (67) Noracymethadol
- \* (68) Norlevorphanol
- \* (69) Normethadone
- \* (70) Norpipanone
- \* (71) Ocfentanil (N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl) acetamide)
- \* (72) Orthofluoroacrylfentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)acrylamide)
- \* (73) Orthomethylacetylfentanyl (N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide)
- \* (74) Orthomethylmethoxyacetylfentanyl (2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl) acetamide)
- \* (75) Para-chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide)
- \* (76) Para-fluorobutyrylfentanyl (N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide)
- \* (77) Para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl] propanamide)
- \* (78) Para-fluorofuranylfentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide)
- \* (79) Para-methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide)
- \* (80) Para-methoxyfuranyl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide)
- \* (81) Para-methylcyclopropyl fentanyl (N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)cyclopropane-carboxamide)
- \* (82) Para-methylfentanyl (N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)propanamide)
- \* (83) PEPAP (1-(-2-phenethyl)-4-phenyl-4-acetoxypiperdine)
- \* (84) Phenadoxone
- \* (85) Phenampromide
- \* (86) Phenomorphan
- \* (87) Phenoperidine
- \* (88) Phenylfentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylbenzamide)
- \* (89) Piritramide
- \* (90) Proheptazine
- \* (91) Properidine
- \* (92) Propiram
- \* (93) Protonitazene (N,N-diethyl-2-[4-propoxyphenyl)methyl]-5-nitro-1H-benimidazole-1-ethanamine)

- \* (94) Racemoramide
- \* (95) Tetrahydrofuranylfentanyl (N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]tetrahydrofuran-2-carboxamide)
- \* (96) Thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl] propanamide)
- \* (97) Thiofuranylfentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylthiophene-2-carboxamide)
- \* (98) Tilidine
- \* (99) Trimeperidine
- \* (100) U-47700 (3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide)
- \* (101) U-48800 (2,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzeneacetamide)
- \* (102) U-49900 (3,4-dichloro-N-[2-(diethylamino)cyclohexyl]-N-methylbenzamide)
- \* (103) U-51754 (3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzeneacetamide)
- \* (104) Valeryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylpentanamide)
- \* (105) Zipeprol (1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol)
- B. Opium Derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
  - \* (1) Acetorphine
  - \* (2) Acetyldihydrocodeine
  - \* (3) Benzylmorphine
  - \* (4) Codeine methylbromide
  - \* (5) Codeine-N-oxide
  - \* (6) Cyprenorphine
  - \* (7) Desomorphine
  - \* (8) Dihydromorphine
  - \* (9) Drotebanol
  - \* (10) Etorphine, except hydrochloride salt
  - \* (11) Heroin
  - \* (12) Hydromorphinol
  - \* (13) Methyldesorphine
  - \* (14) Methyldihydromorphine
  - \* (15) Morphine methylbromide
  - \* (16) Morphine methylsulfonate
  - \* (17) Morphine-N-oxide
  - \* (18) Myrophine
  - \* (19) Nicocodeine
  - \* (20) Nicomorphine
  - \* (21) Normorphine
  - \* (22) Pholcodine
  - \* (23) Thebacon
- C. Hallucinogenic Substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, or salts of isomers whenever the existence of such salts, isomers, or salts of isomers is possible within the specific chemical designation; for purposes of this Subsection only, the term "isomer" includes the optical, position, and geometric isomers:
  - (1) Alpha-ethyltryptamine
  - (2) Alphamethyltryptamine
  - (3) 5-(2-aminopropyl)-2,3-dihydrobenzofuran (5-APDB)
  - (4) 6-(2-aminopropyl)-2,3-dihydrobenzofuran (6-APDB)
  - (5) 5-(2-aminopropyl)benzofuran (5-APB)
  - (6) 6-(2-aminopropyl)benzofuran (6-APB)
  - (7) 4-bromo-2,5-dimethoxyamphetamine
  - (8) 4-bromo-2,5-dimethoxyphenethylamine
  - (9) 4-bromo-2,5-dimethoxyphenethylamine (2C-B)
  - (10) Bufotenine
  - (11) 4-chloro-2,5-dimethoxyamphetamine
  - (12) Deschloroketamine (2-phenyl-2(methylamino) cyclohexanone)
  - (13) Deschloro-N-ethyl-ketamine (2-(ethylamino)-2-phenylcyclohexan-1-one)
  - (14) Diethyltryptamine
  - (15) Diisopropyltryptamine (DIPT)
  - (16) 2,5-dimethoxy-4-chlorophenethylamine (2C-C)

- (17) 2,5-dimethoxy-4-ethylamphetamine
- (18) 2,5-dimethoxy-4-ethylphenethylamine (2C-E)
- (19) 2,5-dimethoxy-4-ethylthiophenethylamine (2C-T-2)
- (20) 2,5-dimethoxy-4-iodophenethylamine (2C-I)
- (21) 2,5-dimethoxy-4-isopropylthiophenethylamine (2C-T-4)
- (22) 2,5-dimethoxy-4-methylphenethylamine (2C-D)
- (23) 2,5-dimethoxy-4-methylthiophenethylamine (2C-T)
- (24) 2,5-dimethoxy-4-nitrophenethylamine (2C-N)
- (25) 2,5-dimethoxy-4-(n)-propylphenethylamine (2C-P)
- (26) 2,5-dimethoxy-4-(n)-propylthiophenethylamine (2C-T-7)
- (27) 2,5-dimethoxyamphetamine
- (28) 2,5-dimethoxyphenethylamine (2C-H)
- (29) Dimethyltryptamine
- (30) Ethylamine analog of phencyclidine
- (31) 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexanone (Methoxetamine)
- (32) 4-Fluoroamphetamine (4-FA)
- (33) 4-Fluoromethamphetamine (4-FMA)
- (34) 4-hydroxy-N,N-diisopropyltryptamine (4-HO-DIPT)
- (35) 4-hydroxy-N-methyl-N-isopropyltryptamine (4-Hydroxy-MIPT)
- (36) Ibogaine
- (37) 5-iodo-2-aminoindane (5-IAI)
- (38) 4-iodo-2,5-dimethoxyamphetamine
- (39) Lysergic acid diethylamide
- (40) Marihuana
- (41) Mescaline
- (42) 4-methoxyamphetamine
- (43) 5-methoxy-alpha-methyltryptamine (5-MEO-AMT)
- (44) 5-methoxy-3,4-methylenedioxyamphetamine
- (45) 5-methoxy-N,N-diallyl-tryptamine (5-MEO-DALT)
- (46) 5-methoxy-N,N-diethyltryptamine (5-MEO-DET)
- (47) 5-methoxy-N, N-diisopropyltryptamine
- (48) 5-methoxy-N,N-dimethyltryptamine (5-MEO-DMT)
- (49) 5-methoxy-N-methyl-N-isopropyltryptamine (5-MEO-MIPT)
- (50) 4-methyl-2,5-dimethoxyamphetamine
- (51) 5-(2-methylaminopropyl)benzofuran (5-MAPB)
- (52) 5,6-methylenedioxy-2-aminoindane (MDAI)
- (53) 3,4-methylenedioxyamphetamine
- (54) 3,4-methylenedioxymethamphetamine (MDMA)
- (55) 3,4-methylenedioxy-N-ethylamphetamine
- (56) N-ethyl-3-piperidyl benzilate
- (57) N-hydroxy-3,4-methylenedioxyamphetamine
- (58) N-(2-hydroxybenzyl)-2,5-dimethoxy-4-iodophenethylamine (25I-NBOH)
- (59) N-(2-methoxybenzyl)-2,5-dimethoxy-4-bromophenethylamine (25B-NBOMe)
- (60) N-(2-methoxybenzyl)-2,5-dimethoxy-4-chlorophenethylamine (25C-NBOMe)
- (61) N-(2-methoxybenzyl)-2,5-dimethoxy-4-iodophenethylamine (25I-NBOMe)
- (62) N-methyl-3-piperidyl benzilate
- (63) Parahexyl, also known as Synhexyl
- (64) Para-methoxymethamphetamine (PMMA)
- (65) Peyote
- (66) Psilocybin
- (67) Psilocyn
- (68) Pyrrolidine analog of phencyclidine
- (69) Tetrahydrocannabinols, including synthetic equivalents and derivatives, except for tetrahydrocannabinols in
- (70) 1-[1-(2-thienyl)cyclohexyl]pyrrolidine
- (71) Thiophene analog of phencyclidine
- (72) 3,4,5-trimethoxy amphetamine
- D. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central

nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Bromazolam
- (2) Clonazolam
- (3) Diclazepam
- (4) Etizolam
- (5) Flualprazolam
- (6) Flubromazolam
- (7) Gamma-hydroxybutyric acid (GHB)
- (8) Mecloqualone
- (9) Methaqualone
- (10) Phenazepam
- E. Stimulants. Unless specifically excepted, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, esters, or ethers and salts of isomers, esters, or ethers whenever the existence of such salts, isomers, esters, or ethers and salts of isomers, esters, or ethers is possible within the specific chemical designation:
  - (1) Amineptine (7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid)
  - (2) 2-amino-1-phenyl-1-propanone (cathinone) or variation in any of the following ways:
    - (i) By substitution on the phenyl ring to any extent with an alkyl, hydroxyl alkoxy, alkylenedioxy, haloalkyl or halide substituents, whether or not further substituted on the phenyl ring by one or more other univalent substituents.
    - (ii) By substitution at the 3-position with an alkyl substituent.
    - (iii) By substitution at the 2-amino nitrogen atom with alkyl, cycloalkyl, dialkyl, benzyl, or methoxybenzyl groups, or by inclusion of the 2-amino nitrogen atom in a cyclic structure.
  - (3) Aminorex
  - (4) Cathinone
  - (5) 4,4-dimethylaminorex (4,4-DMAR)
  - (6) Fenethylline
  - (7) Mesocarb (N-phenyl-N'-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate)
  - (8) Methcathinone
  - (9) Methiopropamine (N-methyl-1-(thiophen-2-yl)propane-2-amine)
  - (10) ( $\pm$ ) cis-4-methylaminorex
  - (11) Naphthylpyrovalerone whether or not further substituted on the naphthyl ring to any extent with alkyl, alkoxy, alkylenedioxy, haloalkyl or halide substituents, whether or not further substituted on the naphthyl ring by one or more other univalent substituents or whether or not further substituted on the carbon chain at the 3, 4, or 5 position with an alkyl substituent.
  - (12) N-benzylpiperazine (BZP)
  - (13) N-ethylamphetamine
  - (14) N, N-dimethylamphetamine
  - (15) 2-(pyrrolidin-1-yl)-1-(thiophen-2-yl)butan-1-one (Alpha-PBT)
  - (16) 2-(pyrrolidin-1-yl)-1-(thiophen-2-yl)pentan-1-one (Alpha-PVT)
- F. Synthetic Cannabinoids. Unless specifically excepted, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of a synthetic cannabinoid found to be in any of the following individual compounds or chemical groups, or any of those individual compounds or groups which contain any synthetic cannabinoid salts, isomers, salts of isomers, or nitrogen-heterocyclic analogs, whenever the existence of such salts, isomers, salts of isomers, or nitrogen-heterocyclic analogs is possible within the specific compounds or chemical groups:
  - Adamantoylindoles: any compound containing a 3-(1-adamantoyl)indole structure, whether or not further substituted on the indole ring to any extent or whether or not substituted on the adamantyl ring to any extent.
  - (2) Adamantylamidoindoles: any compound containing a N-(adamantyl)-1H-indole-3-carboxamide structure, whether or not further substituted on the indole ring to any extent or whether or not substituted on the adamantyl ring to any extent.
  - (3) Benzoylindoles: any compound containing a 3-(benzoyl)indole structure, whether or not substituted on the indole ring to any extent or whether or not substituted on the phenyl ring to any extent.

- (4) Benzylindolecarboxamides: any compound containing a N-benzyl-1H-indole-3-carboxamide structure, whether or not further substituted on the indole ring or whether or not substituted on the phenyl ring to any extent.
- (5) Butaldehydeamidoindoles: any compound containing a N-(1-oxobutan-2yl)-1H-indole-3-carboxamide structure, with or without substitution on the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkoxy, aryl, aryl halide, alkylarylhalide, cycloalkylmethyl, cycloalkylethyl, alkenyl, haloalkenyl, aliphatic alcohol, hydroxyl, halide, morpholinoethyl, alkylmorpholinomethyl, alkylpiperidinylmethyl or a tetrahydropyranylmethyl group, whether or not further substituted on the butaldehyde group to any extent.
- (6) Cumylindolecarboxamides: any compound containing a N-(2-phenylpropane-2-yl)-1H-indole-3-carboxamide structure, with or without substitution on the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkoxy, aryl, aryl halide, alkylarylhalide, cycloalkylmethyl, cycloalkylethyl, alkenyl, haloalkenyl, aliphatic alcohol, hydroxyl, halide, morpholinoethyl, alkylmorpholinomethyl, alkylpiperidinylmethyl, or a tetrahydropyranylmethyl group, whether or not further substituted on the phenyl group to any extent.
- (7) Cyclohexylphenols: any compound containing a 2-(3-hydroxycyclohexyl)phenol structure, whether or not substituted on the cyclohexyl ring to any extent or whether or not substituted on the phenyl ring to any extent.
- (8) Cyclopropanoylindoles: any compound containing a 3-(cyclopropanoyl)indole structure, whether or not substituted on the indole ring to any extent or whether or not substituted on the cyclopropyl ring to any extent.
- (9) (1-(5-fluoropentyl)-1H-benzimidazol-2-yl)(naphthalen-1-yl) methanone
- (10) 1-(5-fluoropentyl)N-naphthalen-1-yl)-1H-pyrrolo[3,2-c]pyridine-3-carboxamide
- (11) 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-B]pyridine-3-carboxamide [5FCUMYL-P7AICA]
- (12) Hexahydrodibenzopyrans whether or not substituted on the tricyclic ring system to any extent except where contained in cannabis or cannabis resin.
- (13) 1-methoxy-3,3-dimethyl-1-oxobutanyl-2yl-(1-cyclohexylmethyl)-1H-indazole-3-carboxylate
- (14) (4-methylpiperazin-1-yl)(1-pentyl-1H-indol-3-yl) methanone
- (15) Naphthalene-1-yl(9-(5-fluoropentyl)-9H-carbazol-3-yl) methanone
- (16) Naphthalene-1-yl(9-pentyl-9H-carbazol-3-yl) methanone
- (17) Naphthoylindoles: any compound containing a 3-(1-naphthoyl)indole structure, whether or not substituted on the indole ring to any extent or whether or not substituted on the naphthyl ring to any extent.
- (18) Naphthoylpyrroles: any compound containing a 3-(1-naphthoyl)pyrrole structure, whether or not substituted on the pyrrole ring to any extent or whether or not substituted on the naphthyl ring to any extent.
- (19) Naphthylamidoindoles: any compound containing a N-(naphthyl)-1H-indole-3-carboxamide structure, whether or not further substituted on the indole ring to any extent or whether or not substituted on the naphthyl ring to any extent.
- (20) Naphthylindolecarboxylates: any compound containing a naphthyl-1H-indole-3-carboxylate structure, whether or not further substituted on the indole ring or whether or not substituted on the naphthyl ring to any extent.
- (21) Naphthylmethylindenes: any compound containing a 1-(1-naphthylmethyl)indene structure, whether or not substituted on the indene ring to any extent or whether or not substituted on the naphthyl ring to any extent.
- (22) Naphthylmethylindoles: any compound containing a 1-H-indol-3-yl-(1-naphthyl)methane structure, whether or not substituted on the indole ring to any extent or whether or not substituted on the naphthyl ring to any extent.
- (23) N-fenchyl-1-[2-(morpholin-4-yl)ethyl]-7-methoxyindole-3-carboxamide
- (24) 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indole-1-one [Cumyl-Pegaclone; SGT-151]
- (25) Phenylacetylindoles: any compound containing a 3-phenylacetylindole structure, whether or not substituted on the indole ring to any extent or whether or not substituted on the phenyl ring to any extent.
- (26) Phenylindolecarboxamides: any compound containing a N-phenyl-1H-indole-3-carboxamide structure, whether or not further substituted on the indole ring or whether or not substituted on the phenyl ring to any extent.
- (27) Phenylpropionaldehydeamidoindoles: any compound containing a N-(1-oxo-3-phenylpropan-2yl)-1H-indole-3-carboxamide structure, with or without substitution in the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkoxy, aryl, aryl halide, alkylarylhalide, cycloalkylmethyl, cycloalkylethyl, alkenyl, haloalkenyl, aliphatic alcohol, hydroxyl, halide, morpholinoethyl, alkylmorpholinomethyl, alkylpiperidinylmethyl or a tetrahydropyranylmethyl group, whether or not further substituted on the phenylpropionaldehyde group to any extent.
- (28) Quinolinylindolecarboxamides: any compound containing a N-quinolinyl-1H-indole-3-carboxamide or N-isoquinolinyl-1H-indole-3-carboxamide structure, whether or not further substituted on the indole,

- quinloline, or the isoquinoline ring to any extent.
- (29) Quinolinylindolecarboxylates: any compound containing a quinolin-8-yl-1H-indole-3-carboxylate or isoquinoline-8-yl-1H-indole-3-carboxylate structure, whether or not further substituted on the indole, quinloline, or isoquinoline ring to any extent.
- (30) Tetrahydrodibenzopyrans whether or not substituted on the tricyclic ring system to any extent except where contained in cannabis or cannabis resin.
- G. Miscellaneous. Unless specifically excepted or contained within a pharmaceutical product approved by the United States Food and Drug Administration, or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substance, including its salts, isomers, or salts of isomers, whenever the existence of such salts, isomers, or salts of isomers is possible within the specific chemical designation:
  - (1) Tianeptine.
- \* NOTE: Asterisks in Schedule I(A) and (B) indicate substances which are narcotics.

### Schedule II

- A. Substances of vegetable origin or chemical synthesis. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
  - (1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, naldemedine, nalmefene, naloxegol, naloxone, 6β-naltrexol, naltrexone, and samidorphan, and their respective salts, but including the following:
    - (a) Raw opium
    - (b) Opium extracts
    - (c) Opium fluid extracts
    - (d) Powdered opium
    - (e) Granulated opium
    - (f) Tincture of opium
    - (g) (Subparagraph (1)(g) repealed by Act 755 of the 1999 Regular Session)
    - (h) Codeine
    - (i) Dihydroetorphine
    - (j) Ethylmorphine
    - (k) Etorphine hydrochloride
    - (1) Hydrocodone
    - (m) Hydromorphone
    - (n) Metopon
    - (o) Morphine
    - (p) Oxycodone
    - (q) Oxymorphone
    - (r) Thebaine
    - (s) Oripavine
  - (2) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in Paragraph (1) above, except that these substances shall not include the isoquinoline alkaloids of opium.
  - (3) Opium poppy and poppy straw.
  - (4) Coca leaves, and any salt, compound, derivative, or preparation of coca leaves (including cocaine, ecgonine and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include:
    - (a) Decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine.
    - (b) Ioflupane, with and without radioisotopes.
  - (5) (Paragraph (5) repealed by Act 282 of the 2001 Regular Session)
  - (6) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).
- B. Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, ethers whenever the existence of such isomers, esters, ethers, or salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(1) Alfentanil

- (2) Alphaprodine
- (3) Anileridine
- (4) Bezitramide
- (5) Bulk Dextropropoxyphene (non-dosage forms)
- (6) Carfentanil
- (7) Dihydrocodeine
- (8) Diphenoxylate
- (9) Fentanyl
- (10) Isomethadone
- (11) Levo-alphacetylmethadol
- (12) Levomethorphan
- (13) Levorphanol
- (14) Metazocine
- (15) Methadone
- (16) Methadone-intermediate, 4-cyano-2-dimethylamino-4, 4-diphenylbutane
- (17) Moramide-intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid
- (18) Oliceridine
- (19) Pethidine (meperidine)
- (20) Pethidine-intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine
- (21) Pethidine-intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate
- (22) Pethidine-intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid
- (23) Phenazocine
- (24) Piminodine
- (25) Racemethorphan
- (26) Racemorphan
- (27) Remifentanil
- (28) Sufentanil
- (29) Tapentadol
- (30) Thiafentanil
- C. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:
  - (1) Amphetamine, its salts, optical isomers, and salts of optical isomers
  - (2) Methamphetamine, its salts, isomers, and salts of its isomers
  - (3) Phenmetrazine and its salts
  - (4) Methylphenidate
  - (5) (Paragraph (5) repealed by Act 755 of the 1999 Regular Session)
  - (6) (Paragraph (6) repealed by Act 755 of the 1999 Regular Session)
  - (7) Lisdexamfetamine, its salts, isomers, and salts of its isomers
- D. (1) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, or salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
  - (a) Amobarbital
  - (b) Carisoprodol (transferred from Schedule IV to Schedule II by Act 397 of the 2014 Regular Session)
  - (c) Glutethimide
  - (d) Pentobarbital
  - (e) Phencyclidine
  - (f) Secobarbital
  - (2) A wholesale drug distributor licensed by the Louisiana Board of Pharmacy and registered with the United States Drug Enforcement Administration shall be exempt from the storage, reporting, record keeping, and physical security requirements for any material, mixture, compound, or preparation which contains any quantity of Carisoprodol.
- E. Immediate Precursors
  - (1) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:
    - (a) Immediate precursors to amphetamine and methamphetamine: phenylacetone
    - (b) Immediate precursors to phencyclidine (PCP):
      - (i) 1-phenylcyclohexylamine

- (ii) 1-piperidinocyclohexanecarbonitrile (PCC)
- (c) Immediate precursor to fentanyl:
  - (i) 4-anilino-N-phenethyl-4-piperidine (ANPP)
  - (ii) Norfentanyl (N-phenyl-N-(piperidin-4-yl)propionamide)
- (2) For purposes of this Subsection, possession of immediate precursors sufficient for the manufacture of phenylacetone, piperidine, or cyclohexanone shall be deemed to be possession of such a derivative substance.
- F. Hallucinogenic Substances
  - (1) Nabilone
  - (2) Dronabinol [delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the United States Food and Drug Administration.

### Schedule III

- A. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:
  - (1) Benzphetamine
  - (2) Chlorphentermine
  - (3) Clortermine
  - (4) (Paragraph (4) repealed by Act 92 of the 1982 Regular Session)
  - (5) (Paragraph (5) repealed by Act 67 of the 2008 Regular Session)
  - (6) Phendimetrazine
- B. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:
  - (1) Any compound, mixture, or preparation containing:
    - (a) Amobarbital
    - (b) Secobarbital
    - (c) Pentobarbital or any salt thereof and one or more active medicinal ingredients which are not listed in any schedule.
  - (2) Any suppository dosage form containing:
    - (a) Amobarbital
    - (b) Secobarbital
    - (c) Pentobarbital or any salt of any of these drugs and approved by the federal Food and Drug Administration for marketing only as a suppository.
  - (3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt thereof, but not including butalbital when in combination with at least three hundred twenty-five milligrams of acetaminophen per dosage unit.
  - (4) Chlorhexadol
  - (5) Embutramide
  - (6) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, which has been approved by the federal Food and Drug Administration.
  - (7) Ketamine, its salts, isomers, and salts of isomers
  - (8) Lysergic acid
  - (9) Lysergic acid amide
  - (10) Methyprylon
  - (11) Sulfondiethylmethane
  - (12) Sulfonethylmethane
  - (13) Sulfonmethane
  - (14) Tiletamine and zolazepam or any salt thereof
  - (15) Perampanel
- C. Nalorphine
- D. Limited Narcotic Drugs. Unless specifically excepted or unless listed in another schedule:
  - (1) Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:
    - (a) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit with an equal or greater quantity of an isoquinoline alkaloid of opium.
    - (b) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

- (c) (Subparagraph (1)(c) repealed by Act 189 of the 2015 Regular Session)
- (d) (Subparagraph (1)(d) repealed by Act 189 of the 2015 Regular Session)
- (e) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (f) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (g) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (h) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (2) Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts:
  - (a) Buprenorphine
- E. Anabolic steroids and muscle building substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, containing any quantity of the following substances, including its salts, esters, ethers, isomers, and salts of isomers whenever the existence of such salts, esters, ethers, isomers, and salts of isomers is possible within the specific chemical designation. The term "anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone that promote muscle growth and include the following:
  - (1) 3β, 17-dihydroxy-5a-androstane
  - (2)  $3\alpha$ ,  $17\beta$ -dihydroxy-5a-androstane
  - (3)  $5\alpha$ -androstan-3, 17-dione
  - (4) 3β, 17β-dihydroxy- $5\alpha$ -androst-1-ene
  - (5)  $3\alpha$ ,  $17\beta$ -dihydroxy- $5\alpha$ -androst-1-ene
  - (6) 4-androstenediol
  - (7) 5-androstenediol
  - (8) 1-androstenedione
  - (9) 4-androstenedione
  - (10) 5-androstenedione
  - (11) Bolasterone
  - (12) Boldenone
  - (13) Boldione
  - (14) Calusterone
  - (15) Clostebol
  - (16) Dehydrochloromethyltestosterone
  - (17) Desoxymethyltestosterone
  - (18)  $\Delta$ 1-dihydrotestosterone
  - (19) 4-dihydrotestosterone
  - (20) Drostanolone
  - (21) Ethylestrenol
  - (22) Fluoxymesterone
  - (23) Formebolone
  - (24) Furazebol
  - (25) 13β-ethyl-17α-hydroxygon-4-en-3-one
  - (26) 4-hydroxytestosterone
  - (27) 4-hydroxy-19-nortestosterone
  - (28) Mestanolone
  - (29) Mesterolone
  - (30) Methandienone
  - (31) Methandriol
  - (32) Methasterone (2,  $17\alpha$ -dimethyl- $5\alpha$ -androstan- $17\alpha$ -ol-3-one)
  - (33) Methenolone
  - (34)  $17\alpha$ -methyl-3 $\beta$ ,  $17\beta$ -dihydroxy-5 $\alpha$ -androstane
  - (35) 17α-methyl-3α, 17β-dihydroxy-5a-androstane
  - (36) 17α-methyl-3β, 17β-dihydroxyandrost-4-ene
  - (37) 17α-methyl-4-hydroxynandrolone
  - (38) Methyldienolone

- (39) Methyltrienolone
- (40) Methyltestosterone
- (41) Mibolerone
- (42)  $17\alpha$ -methyl- $\Delta 1$ -dihydrotestosterone
- (43) Nandrolone
- (44) 3β, 17β-dihydroxyestr-4-ene
- (45) 3α, 17β-dihydroxyestr-4-ene
- (46) 3β, 17β-dihydroxyestr-5-ene
- (47)  $3\alpha$ ,  $17\beta$ -dihydroxyestr-5-ene
- (48) 19-nor-4,9(10)-androstadienedione
- (49) 19-nor-4-androstenedione
- (50) 19-nor-5-androstenedione
- (51) Norbolethone
- (52) Norclostebol
- (53) Norethandrolone
- (54) Normethandrolone
- (55) Oxandrolone
- (56) Oxymesterone
- (57) Oxymetholone
- (58) Prostanozol (17α-hydroxy-5α-androstano[3,2-c]pyrazole)
- (59) Stanozolol
- (60) Stenbolone
- (61) Testolactone
- (62) Testosterone
- (63) Tetrahydrogestrinone
- (64) Trenbolone
- F. (1) Except as provided in Paragraph (2) of this Subsection, the term *anabolic steroid* does not include a substance listed in Subsection E above but which is expressly intended for administration to livestock or other nonhuman species and which has been approved by the secretary for such administration.
  - (2) If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of Subsection E of this Schedule.
  - (3) A physician, dentist, or veterinarian shall not prescribe, dispense, deliver, or administer an anabolic steroid for human use or cause an anabolic steroid to be administered under his direction or supervision for human use except for a valid medical purpose and when required by demonstrable generally accepted medical indications. Bodybuilding, muscle enhancement, or increasing muscle bulk or strength through the use of an anabolic steroid by a person who is in good health is hereby declared not a valid medical purpose.
- G. Substances of vegetable origin or chemical synthesis. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
  - (1) Synthetic dronabinol [delta-9-(trans) tetrahydrocannabinol] in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved product.

### Schedule IV

- A. Narcotic Drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts, in limited quantities, as set forth below:
  - (1) Not more than 1 milligram of different and not less than 25 micrograms of atropine sulfate per dosage unit.
  - (2) Dextropropoxyphene.
  - (3) Tramadol (2-[(dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol), its salts, isomers, and salts of its isomers.
- B. Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
  - (1) Alfaxalone
  - (2) Alprazolam
  - (3) Barbital

- (4) Brexanolone
- (5) Bromazepam
- (6) Camazepam
- (7) Chloral betaine
- (8) Chloral hydrate
- (9) Chlordiazepoxide, but not including chlordiazepoxide hydrochloride in combination with clidinium bromide, or chlordiazepoxide and water-soluble esterified estrogens
- (10) Clobazam
- (11) Clonazepam
- (12) Clorazepate
- (13) Clotiazepam
- (14) Cloxazolam
- (15) Daridorexant
- (16) Delorazepam
- (17) Diazepam
- (18) Dichloralphenazone
- (19) Estazolam
- (20) Ethchorvynol
- (21) Ethinamate
- (22) Ethyl loflazepate
- (23) Fludiazepam
- (24) Flunitrazepam
- (25) Flurazepam
- (26) Fospropofol
- (27) Halazepam
- (28) Haloxazolam
- (29) Ketazolam
- (30) Lemborexant
- (31) Loprazolam
- (32) Lorazepam
- (33) Lormetazepam
- (34) Mebutamate
- (35) Medazepam
- (36) Meprobamate
- (37) Methohexital
- (38) Methylphenobarbital (mephobarbital)
- (39) Midazolam
- (40) Nimetazepam
- (41) Nitrazepam
- (42) Nordiazepam
- (43) Oxazepam
- (44) Oxazolam
- (45) Paraldehyde
- (46) Petrichloral
- (47) Phenobarbital
- (48) Pinazepam
- (49) Prazepam
- (50) Quazepam
- (51) Remimazolam
- (52) Suvorexant
- (53) Temazepam
- (54) Tetrazepam
- (55) Triazolam
- (56) Zaleplon
- (57) Zolpidem(58) Zopiclone
- (59) Zuranolone
- C. (Subsection C repealed by Act 201 of the 2023 Regular Session)
- D. Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or

preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers:

- (1) Cathine (norpseudoephedrine)
- (2) Diethylpropion
- (3) Fencamfamin
- (4) Fenproporex
- (5) Lorcaserin
- (6) Mazindol
- (7) Mefenorex
- (8) Modafinil
- (9) Pemoline (including organometallic complexes and chelates thereof)
- (10) Phentermine
- (11) Pipradol
- (12) Serdexmethylphenidate
- (13) Sibutramine
- (14) Solriamfetol (2-amino-3-phenylpropyl carbamate; benzenepropanol, beta-amino-, carbamate (ester)
- (15) SPA [(-)-1-dimethylamino-1,2-diphenylethane]
- E. Other Substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts:
  - (1) Pentazocine
  - (2) Butorphanol (including its optical isomers)
  - (3) Eluxadoline (5-[[[2-amino-3-[(4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][1-(4-phenyl-1H-imidazol-2-yl)theyl]amino]methyl]-2-methoxybenzoic acid)(including its optical isomers) and its salts, isomers, and salts of isomers.
- F. Mifepristone, Misoprostol. Unless listed in another schedule, any material, compound, mixture, or preparation containing any detectable quantity of mifepristone or misoprostol.

#### Schedule V

- A. Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:
  - (1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.
  - (2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.
  - (3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.
  - (4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
  - (5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.
  - (6) Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.
- B. Narcotic Drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts, as set forth below:
  - (1) (Paragraph (1) repealed by Act 54 of the 2006 Regular Session)
- C. Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:
  - (1) Pyrovalerone
- D. Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:
  - (1) Brivaracetam (2-[2-oxo-4-propylpyrrolidin-1-yl]butanamide), also referred to as BRC; UCB-34714; Briviact
  - (2) Cenobamate (1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethylcarbamate)
  - (3) Ezogabine
  - (4) Ganaxolone (3-α-hydroxy-3-β-methyl-5-α-pregnan-20-one)
  - (5) Lacosamide
  - (6) Lasmiditan (2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide)
  - (7) Pregabalin
- E. (1) Ephedrine, pseudoephedrine, phenylpropanolamine. Unless listed in another schedule, any material, compound, mixture, or preparation containing any detectable quantity of ephedrine, pseudoephedrine, or

- phenylpropanolamine, their salts or optical isomers, or salts of optical isomers.
- (2) (a) Nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine shall not be sold or distributed in a quantity greater than nine grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base to the same purchaser within any thirty-day period.
  - (b) Notwithstanding the prescription requirements for Schedule V controlled dangerous substances as provided for in R.S. 40:978(C), nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine may be dispensed without a prescription.
- (3) (a) No person shall purchase, receive, or otherwise acquire more than nine grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base within any thirty-day period.
  - (b) This limit shall not apply to any quantity of such product, mixture, or preparation dispensed pursuant to a valid prescription written by a licensed healthcare professional having prescriptive authority.
- (4) Wholesale drug distributors licensed by the Louisiana Board of Drug and Device Distributors and registered with the United States Drug Enforcement Administration shall be exempt from the storage, reporting, record keeping, and physical security requirements for controlled dangerous substances for nonprescription products containing ephedrine, pseudoephedrine, and phenylpropanolamine which are not listed in another schedule.
- (5) Except for sales log requirements and the transmittal of transaction information to the central computer monitoring system authorized by the provisions of <a href="Part X-F">Part X-F</a> of Chapter 4 of Title 40 of the Louisiana Revised Statutes of 1950, pharmacies and pharmacists licensed by the Louisiana Board of Pharmacy and registered with the United States Drug Enforcement Administration shall be exempt from the storage, reporting, record keeping, and physical security requirements for controlled dangerous substances for nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine which are not listed in another schedule.
- (6) The transaction information provided for in R.S. 40:1049.3 for the purchase of a nonprescription product containing ephedrine, pseudoephedrine, or phenylpropanolamine shall constitute an "order from a practitioner" as provided for in R.S. 40:970(C). Possession of a nonprescription product containing ephedrine, pseudoephedrine, or phenylpropanolamine pursuant to a valid transaction as provided for in R.S. 40:1049.3 shall be a defense for a violation of R.S. 40:970(C).
- F. (Subsection F repealed by Act 101 of the 2021 Regular Session)

(Schedules amended by Act 92 of the 1982 Regular Session; Acts 513 and 842 of the 1991 Regular Session; Acts 156, 288, and 616 of the 1993 Regular Session; Act 398 of the 1997 Regular Session; Act 129 of the 1998 First Extraordinary Session; Acts 582 and 755 of the 1999 Regular Session; Act 13 of the 2000 First Extraordinary Session; Acts 282 and 1036 of the 2001 Regular Session; Act 702 of the 2004 Regular Session; Acts 54 and 56 of the 2006 Regular Session; Act 67 of the 2008 Regular Session; Acts 153, 165 and 314 of the 2009 Regular Session; Act 810 of the 2010 Regular Session; Act 420 of the 2011 Regular Session; Acts 315 and 345 of the 2012 Regular Session; Acts 7 and 8 of the 2013 Regular Session; Acts 40, 43 and 397 of the 2014 Regular Session; Acts 189 and 373 of the 2015 Regular Session; Act 62 of the 2016 Regular Session; Act 100 of the 2017 Regular Session; Acts 119 and 206 of the 2018 Regular Session; Act 354 of the 2019 Regular Session; Act 10 of the 2020 Regular Session; Act 101 of the 2021 Regular Session; Acts 46 and 201 of the 2022 Regular Session; Act 201 of the 2023 Regular Session; Acts 110, 143, 246 and 732 of the 2024 Regular Session)

### §964.1. Treatment of controlled analogues

A controlled substance analogue shall be treated, for the purposes of any state law and to the extent intended for human consumption, as a controlled dangerous substance in either Schedule I or Schedule II of R.S. 40:964. (Section added by Act 34 of the 1994 Regular Session; amended by Act 1036 of the 2001 Regular Session)

### §965. Secretary of department of health; authority to except

- A. The secretary may by regulation except any material, compound, mixture, or preparation containing any depressant or stimulant substance listed in Subsection A, B, C, or D of Schedule III or in Schedule IV or V from the application of all or any part of this Part if the material, compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant or stimulant effect on the central nervous system, provided that such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a depressant or stimulant effect on the central nervous system.
- B. The secretary may, by regulation, exempt any compound, mixture, or preparation containing any anabolic steroid substances listed in Schedule III(E) of <u>R.S. 40:964</u> from the application of all or any part of this Part if, because of its concentration, preparation, mixture, or delivery system, it has no significant potential for abuse.

(Section amended by Act 513 of the 1991 Regular Session; Act 206 of the 2018 Regular Session)

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### §971. Prohibited acts – all schedules

- A. (1) It shall be unlawful for any person:
  - (a) Who is subject to the requirements of this Part to distribute or dispense a controlled dangerous substance in violation of this Part; or
  - (b) Who is a licensee to manufacture, distribute, or dispense a controlled dangerous substance to another licensee or other authorized person not authorized by his license; or
  - (c) To omit, remove, alter, or obliterate a symbol required by the Uniform Controlled Dangerous Substances Law; or
  - (d) To refuse or fail to make, keep, or furnish any record, notification, order form, statement, invoice, or information required under this Part; or
  - (e) To refuse entry into any premise for inspection as authorized by this Part; or
  - (f) To keep or maintain any store, shop, warehouse, dwelling house, building, vehicle, boat, aircraft, or any place whatever, which is frequented by persons using controlled dangerous substances in violation of this Part for the purpose of using such substances, or which is used for the keeping or selling of the same in violation of this Part.
  - (2) Any person who violates this subsection shall be fined not more than fifteen thousand dollars. Such proceeding shall be independent, and not in lieu of, other proceedings under this part or any other law of this state. If the violation is prosecuted by a bill of information or an indictment which alleges that the violation was committed knowingly or intentionally, such person, upon conviction, shall be imprisoned for not more than six months; and, in addition, may be sentenced to pay a fine of not more than five hundred dollars.
- B. (1) It shall be unlawful for any person knowingly or intentionally:
  - (a) To use in the course of the manufacture or distribution of a controlled dangerous substance a license number which is fictitious, revoked, suspended, or issued to another person; or
  - (b) To acquire or obtain possession of a controlled dangerous substance by misrepresentation, fraud, forgery, deception, or subterfuge; or
  - (c) To furnish false or fraudulent material, information in any application, report, or other document required to be kept by this Part; or
  - (d) To make, distribute, or possess any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another of any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit controlled dangerous substance; or
  - (e) To alter any controlled dangerous substance obtained by prescription without prior approval of the department; or
  - (f) To alter any prescription for a controlled dangerous substance, provided that this shall not apply to the person issuing the original prescription or the pharmacist pursuant to instructions from the physician; or
  - (g) To obtain or attempt to obtain a prescription or prescription blank form from a doctor, dentist, or veterinarian for a controlled dangerous substance and/or legend drug by fraud, theft, misrepresentation, deception, or subterfuge; or
  - (h) To possess a prescription for a controlled dangerous substance and/or legend drug without the express consent of the party for whom such prescription was written. For the purposes hereof, a legend drug is any drug or drug product bearing on the label of the manufacturer or distributor as required by the federal Food and Drug Administration the statement "Caution: Federal law prohibits dispensing without prescription."
  - (i) To obtain or seek to obtain any controlled dangerous substance or a prescription for a controlled dangerous substance from a health care practitioner, while being supplied with any controlled dangerous substance or a prescription for any controlled dangerous substance by another health care practitioner, without disclosing the fact of the existing prescription to the practitioner from whom the subsequent prescription for a controlled dangerous substance is sought. Failure of a practitioner to request the disclosure is not a violation of this Subsection by the practitioner. The disclosure shall include the name of the controlled dangerous substance, the date of the prescription, the amount of the controlled substance prescribed, and the number of refills if any. The disclosure shall be made in writing by the person obtaining or seeking to obtain the controlled dangerous substance and shall be made a part of the person's medical record by the health care practitioner. As used in this Section, the term "existing" shall mean the period of time within which the prescription was prescribed to be taken.
  - (2) Any person who violates this Subsection shall be imprisoned, with or without hard labor, for not more than five years, and in addition, may be sentenced to pay a fine of not more than five thousand dollars.

- C. (1) It shall be unlawful for a person, including a physician, dentist, podiatrist, or veterinarian, to prescribe, dispense, or administer legally controlled substances beyond his respective prescribing authority or for a purpose other than accepted medical treatment of a disease, condition, or illness.
  - (2) It shall be unlawful for a pharmacist to dispense legally controlled substances beyond his dispensing authority.
  - (3) Any person who violates this Subsection shall be subject to the penalties as established for the controlled dangerous substance and the particular criminal act committed in R.S. 40:966 through 967.
- D. Every practitioner, as defined in <u>R.S. 40:961(35)</u>, may, if he has a good faith belief that a crime has been committed on the premises, notify local law enforcement authorities when it is believed that an individual has obtained a fraudulent prescription for any controlled dangerous substance or any person has attempted to obtain a fraudulent prescription for any controlled dangerous substance.
- E. Every pharmacy in which a controlled dangerous substance is physically obtained by a patient or a patient's agent shall require every person purchasing, receiving, or otherwise acquiring any controlled dangerous substance to produce a photo identification card, unless the patient or the patient's agent is known to the pharmacist. The person purchasing, receiving, or otherwise acquiring the controlled dangerous substance does not have to be the specific patient to whom the prescription is issued.

(Section amended by Act 207 of the 1973 Regular Session; Acts 613 and 700 of the 1975 Regular Session; Act 786 of the 1978 Regular Session; Act 984 of the 1988 Regular Session; Act 600 of the 2006 Regular Session; Act 287 of the 2007 Regular Session)

### §971.1. Prohibited acts; false representation

- A. It shall be unlawful for any person to produce, manufacture, distribute, dispense, transport, deliver, or possess with intent to distribute or dispense any substance which is represented to be a controlled dangerous substance and which is an imitation controlled dangerous substance, or any controlled dangerous substance which is a counterfeit controlled dangerous substance.
- B. The provisions of this Section shall not apply to a law enforcement officer acting in the course and scope of his employment or to a medical practitioner, pharmacist, or other person authorized to dispense or administer controlled dangerous substances pursuant to this Part.
- C. Any person who violates the provisions of this Section shall be imprisoned, with or without hard labor, for not more than five years, and in addition, may be fined not more than five thousand dollars.

(Section added by Act 914 of the 1981 Regular Session; amended by Act 154 of the 1993 Regular Session; Act 34 of the 1994 Regular Session; Act 530 of the 2010 Regular Session; Act 100 of the 2011 Regular Session; Act 206 of the 2018 Regular Session)

## §971.2. Unlawfully prescribing, distributing, dispensing, or assisting in illegally obtaining controlled dangerous substances

- A. This Section shall be known as and may be cited as the "Pain Management Clinic Drug Abuse and Overdose Prevention Act."
- B. It shall be unlawful for a physician, other licensed health care practitioner as defined in <u>R.S. 40:961(35)</u>, or any other person to knowingly or intentionally commit any of the following acts:
  - (1) Assist a patient or any other person in obtaining a controlled dangerous substance through misrepresentation, fraud, forgery, deception, or subterfuge.
  - (2) Write a prescription for a controlled dangerous substance for a fictitious person.
  - (3) Distribute or dispense a controlled dangerous substance to a fictitious person.
  - (4) Operate any type of business or establishment where the primary purpose of the business or establishment is the sale, exchange, barter, or trade of a controlled dangerous substance for anything of value through misrepresentation, fraud, forgery, deception, or subterfuge.
- C. Whoever violates the provisions of this Section shall be imprisoned, with or without hard labor, for not more than five years, and in addition may be sentenced to pay a fine of not more than fifty thousand dollars. (Section added by Act 25 of the 2005 Regular Session; amended by Act 51 of the 2006 Regular Session)

### §971.3. Misbranding or adulteration of drugs with intent to defraud or mislead

Any person who violates the provisions of <u>R.S. 40:617</u> or <u>R.S. 40:636</u> with respect to any drug, as defined in <u>R.S. 40:602</u>, and with the intent to defraud or mislead, shall be imprisoned, with or without hard labor, for not more than five years, or fined not more than ten thousand dollars, or both.

(Section added by Act 108 of the 2017 Regular Session)

### §972. Rules and regulations and fees

- A. The Louisiana Board of Pharmacy is authorized to promulgate rules and regulations relating to the registration and control of the manufacture, distribution and dispensing of controlled dangerous substances within this state.
- B. The fees collected by the Louisiana Board of Pharmacy for registration and licensing shall not exceed the following schedule:

		<u>Minimum</u>
(1)	Manufacturer	\$100.00
(2)	Ambulatory surgical centers	\$ 50.00
(3)	Emergency medical centers	\$ 50.00
(4)	Hospital	\$ 50.00
(5)	Methadone clinic	\$ 50.00
(6)	Wholesaler / distributor	\$ 50.00
(7)	Third-party logistics provider	\$ 50.00
(8)	Practitioner	\$ 20.00
(9)	Intern / resident	\$ 20.00
(10)	Drug detection / canine	\$ 30.00
(11)	Researcher	\$ 30.00
(12)	Sales representative (or medical service representative or detail person)	\$ 20.00
(13)	Other (schools, laboratories, crime laboratories, coroners, ambulance service	s,
	analytical laboratories, etc.)	\$ 20.00
(14)	Duplicate / Replacement fee	\$ 5.00
(15)	Delinquent fee (30 days after expiration / assessed per year)	\$ 10.00

C. All said fees collected in accordance with the provisions of this Chapter shall be deposited in a separate fund and used for the administration and enforcement of this Part, and for education and research as provided by R.S. 40:992, together with any supplemental funds appropriated by the legislature or federal funds or grants received.

(Section amended by Act 786 of the 1978 Regular Session; Act 834 of the 2006 Regular Session; Acts 186 and 206 of the 2018 Regular Session)

### §973. Licensing requirements

- A. (1) Every person who conducts research with, manufactures, distributes, procures, possesses, prescribes, or dispenses any controlled dangerous substance within this state, including third-party logistics providers, or who proposes to engage in the research, manufacture, distribution, procurement possession, prescribing, or dispensing of any controlled dangerous substance within this state, including third-party logistics providers, shall obtain a controlled substance license issued by the Louisiana Board of Pharmacy in accordance with the rules and regulations promulgated by the board prior to engaging in such activity.
  - (2) Upon initial application or upon renewal of a controlled dangerous substance license from the Louisiana Board of Pharmacy, a prescribing practitioner shall automatically and without further action be registered as a participant in the prescription monitoring program established in <u>R.S. 40:1001</u> et seq. For purposes of this Subsection, the term "practitioner" shall include those with prescription authority for controlled substances in Louisiana, excluding veterinarians.
- B. The following persons shall not be required to obtain a license and may lawfully possess controlled dangerous substances under the provisions of this Part:
  - (1) An agent, or an employee thereof, of any registered manufacturer, distributor, or dispenser of any controlled dangerous substance if such agent is acting in the usual course of his business or employment.
  - (2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled dangerous substance is in the usual course of his business or employment.
  - (3) An ultimate user or person in possession of any controlled dangerous substance pursuant to a lawful order of a practitioner.
- C. The Louisiana Board of Pharmacy may, by regulation, waive the requirement for licensing of certain manufacturers, distributors, or dispensers if it finds it consistent with the public health and safety.
- D. A separate license shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled dangerous substances.
- E. The Louisiana Board of Pharmacy is authorized to inspect the establishment of a licensee or applicant for licensing in accordance with the rules and regulations promulgated by the board.
- F. (1) Any person licensed by the Louisiana Board of Pharmacy to manufacture, distribute, or dispense controlled dangerous substances shall submit to the board data on transactions involving the disbursement of Schedule II controlled dangerous substances to licensed Louisiana registrants except as provided in <u>R.S. 40:972</u> and <u>988(B)</u>.

- (2) The Louisiana Board of Pharmacy is authorized to promulgate rules and regulations necessary to implement the provisions of this Subsection including but not limited to the scope of such data, the form in which it is to be submitted, and the time requirements for such submission.
- G. (1) The Louisiana Board of Pharmacy shall disseminate its findings concerning possible violations to the respective boards for action in correcting violations on the part of licensed Louisiana registrants.
  - (2) (a) Such supervisory board shall receive the findings of the Louisiana Board of Pharmacy concerning possible violations and shall disseminate such findings to the respective boards for action in correcting violations on the part of licensed Louisiana registrants.
    - (b) All expenses for the operation of the supervisory board shall be borne by the licensing boards which make up said supervisory boards.

(Section amended by Act 786 of the 1978 Regular Session; Act 702 of the 1984 Regular Session; Act 662 of the 1989 Regular Session; Act 834 of the 2006 Regular Session; Act 76 of the 2017 Regular Session; Acts 186 and 206 of the 2018 Regular Session)

### §973.1. Louisiana Board of Pharmacy; criminal history record information

- A. For purposes of this Section, the following definitions apply:
  - (1) "Applicant" means an individual who has applied to the board for the issuance or reinstatement of any controlled dangerous substance license that the board is authorized by law to issue.
  - (2) "Board" means the Louisiana Board of Pharmacy.
  - (3) "Bureau" means the Louisiana Bureau of Criminal Identification and Information.
  - (4) "Criminal history record" or "criminal history record information" means information collected by criminal justice agencies on individuals consisting of identifiable descriptions and notations of arrests, detentions, indictments, bills of information, or any formal criminal charges, and any disposition arising therefrom, including sentencing, correctional supervision, and release. The terms do not include information gathered or collected for intelligence or investigatory purposes, nor do the terms include any identification information which does not indicate involvement of the individual in the criminal justice system.
  - (5) "FBI" means the Federal Bureau of Investigation of the United States Department of Justice.
  - (6) "Licensure" means any controlled dangerous substance license that the board is authorized to issue.
- B. In addition to any other requirement established by rule, the board may require an applicant who is not in possession of a valid and verifiable license or other credential from a standing professional board of the state of Louisiana or from the Louisiana Department of Health, bureau of health services financing, health standards, or their successors, to do the following as a condition for eligibility for licensure:
  - (1) Submit fingerprints and other identifying information to the board.
  - (2) Permit the board to request and obtain state and national criminal history record information on the applicant.
- C. (1) The costs of providing the information required under this Section shall be charged by the bureau, as specified in <u>R.S. 15:587</u>, to the board including any additional costs of providing the national criminal history records check for information that pertains to the applicant.
  - (2) The board may impose any or all of such fees or costs on the applicant.
- D. Upon request by the board and upon the board's submission of an applicant's fingerprints and other identifying information as may be required, the bureau shall conduct a search of its criminal history record information relative to the applicant and report the results of its search to the board within sixty days from receipt of such request. Pursuant to R.S. 15:587, the bureau may charge the board a processing fee.
- E. If the criminal history record information reported by the bureau to the board does not provide grounds for disqualification of the applicant for licensure by the board, the board may forward the applicant's fingerprints and other identifying information as may be required to the FBI with a request for a search of national criminal history record information relative to the applicant.
- F. Any state or national criminal history record information that is obtained by the board from the bureau or FBI and that is not already a matter of public record shall not be public record and shall be confidential, restricted to the exclusive use of the board, its members, officers, investigators, agents, and attorneys in evaluating the applicant's eligibility or ineligibility for licensure. No information or record related to the state or national criminal history record information of an applicant shall be released or otherwise disclosed to any other person or agency, except with the written consent of the applicant or by an order of a court of competent jurisdiction.

(Section added by Act 219 of the 2019 Regular Session)

### §974. Licensing

A. The Louisiana Board of Pharmacy shall license an applicant to manufacture or distribute controlled dangerous substances included in Schedules I through V of <u>R.S. 40:964</u> at such fees as it shall determine to be reasonable, unless it determines that the issuance of such license is inconsistent with the public interest. In determining the

public interest, the following factors shall be considered:

- (1) Maintenance of effective controls against diversion of particular controlled dangerous substances and any Schedule I or II substance compounded therefrom into other than legitimate medical, scientific, or industrial channels:
- (2) Compliance with applicable state and local law;
- (3) Prior conviction record of applicant under federal or state laws relating to the manufacture, distribution, or dispensing of such substances
- (4) Past experience in the manufacture of controlled dangerous substances, and the existence in the establishment of effective controls against diversion; and
- (5) Such other factors as are relevant to and consistent with the public health and safety.
- B. Licenses granted under Subsection A of this Section shall not entitle a licensee to manufacture and distribute controlled dangerous substances in Schedule I or II other than those specified in the license.
- C. A license application by a practitioner who wishes to conduct research with a controlled substance shall be referred to the Louisiana Board of Pharmacy. Licensing by the Louisiana Board of Pharmacy for the purpose of bona fide research with a controlled dangerous substance by a practitioner deemed qualified by the board may be denied only on a ground specified in R.S. 40:975(A) or on the ground that the applicant's past practice or proposed procedures furnish grounds for the belief that the applicant will abuse or unlawfully transfer such substances from legitimate medical or scientific use.

(Section amended by Act 786 of the 1978 Regular Session; Act 834 of the 2006 Regular Session; Act 206 of the 2018 Regular Session)

### §975. Denial, revocation, suspension, or termination of license

- A. A license pursuant to <u>R.S. 40:974</u> to manufacture, distribute, or dispense a controlled dangerous substance may be suspended or revoked by the Louisiana Board of Pharmacy upon a finding that the applicant or licensee meets any of the following criteria:
  - (1) He has materially falsified any application filed pursuant to or required by this Part.
  - (2) He has been convicted of a felony under this Part or any law of the United States, or of any state, relating to any substances defined in this Part as a controlled dangerous substance, or any felony under any other law of the United States or of any state within five years of the date of the issuance of the license.
  - (3) His federal license has been suspended or revoked by competent federal authority and he is no longer authorized by federal law to engage in the manufacturing, distribution, or dispensing of controlled dangerous substances.
  - (4) He has manufactured, distributed or dispensed controlled dangerous substances in violation of any provision of this Part or any other state or federal laws pertaining to the manufacture, distribution or dispensing of controlled dangerous substances.
  - (5) He has repeatedly failed to submit to the Louisiana Board of Pharmacy data on transactions involving the disbursement of Schedule II controlled dangerous substances to licensed Louisiana registrants as required by R.S. 40:973(F) and by rules promulgated pursuant thereto.
- B. The Louisiana Board of Pharmacy may limit revocation or suspension of a license to the particular controlled dangerous substance with respect to which grounds for revocation or suspension exist.
- C. Before taking action pursuant to this Section or pursuant to a denial of license under R.S. 40:974, the Louisiana Board of Pharmacy shall serve upon the applicant or licensee an order to show cause why the license should not be denied, revoked, or suspended. The order to show cause shall contain a statement of the basis thereof and shall call upon the applicant or licensee to appear before the Louisiana Board of Pharmacy at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this Section in accordance with R.S. 49:951 et seq. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this Part or any law of the state.
- D. The Louisiana Board of Pharmacy may, in its discretion, suspend any license simultaneously with the institution of proceedings under this Section in cases where it finds that there is an imminent danger to the public health or safety. Such suspension shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Louisiana Board of Pharmacy or dissolved by a court of competent jurisdiction.
- E. In the event the Louisiana Board of Pharmacy suspends or revokes a license granted under R.S. 40:974, all controlled dangerous substances owned or possessed by the licensee pursuant to such license at the time of suspension or the effective date of the revocation order, as the case may be, may in the discretion of the board, be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming

- final, all such controlled dangerous substances shall be forfeited to the state.
- F. The Bureau of Narcotics and Dangerous Drugs shall promptly be notified of all orders suspending or revoking license and all forfeitures of controlled dangerous substances.
- G. (1) A license pursuant to R.S. 40:974 to manufacture, distribute, or dispense a controlled dangerous substance shall be terminated by the Louisiana Board of Pharmacy if the licensee has failed to timely renew the license and submit the applicable fee, including the fee for the prescription monitoring program authorized pursuant to R.S. 40:1013, and thirty days have elapsed since the date of expiration.
  - (2) Any appeal from the provisions of this Subsection shall be governed by the <u>Administrative Procedure Act</u>.
  - (3) The Louisiana Board of Pharmacy shall promulgate rules, regulations, and standards to implement the provisions of this Subsection. The rules, regulations, and standards shall be promulgated in accordance with the <u>Administrative Procedure Act</u>.

(Section amended by Act 608 of the 1978 Regular Session; Act 786 of the 1978 Regular Session; Act 702 of the 1984 Regular Session; Act 62 of the 1997 Regular Session; Acts 676 and 834 of the 2006 Regular Session; Act 206 of the 2018 Regular Session)

### §976. Records of licensees

Each licensee manufacturing, distributing or dispensing controlled dangerous substances in Schedule I, II, III, IV or V shall make a complete and accurate record of all stocks of such dangerous substances on hand. Thereafter, complete and accurate records of all such dangerous substances shall be maintained until the next inventory is made for the next two-year period as required by this Section. At each two-year period after July 29, 1970, at the time of his regular physical inventory, each licensee manufacturing, distributing, or dispensing controlled dangerous substances shall prepare an inventory of each dangerous substance in his possession. Records and inventories shall contain such information as shall be provided by rules and regulations promulgated by the Louisiana Board of Pharmacy. This Section shall not apply to practitioners who lawfully prescribe or administer, but do not otherwise dispense, controlled dangerous substances listed in Schedule II, III, IV or V of this Part.

(Section amended by Act 786 of the 1978 Regular Session; Act 834 of the 2006 Regular Session; Act 206 of the 2018 Regular Session)

### §976.1. Chemical precursor, recordkeeping requirements

- A. A manufacturer, wholesaler, retailer, or other person who sells, transfers, or otherwise furnishes any of the following precursor substances shall make an accurate and legible record of the transaction and maintain the record for a period of at least five years after the date of the transaction:
  - (1) Methylamine
  - (2) Ethylamine
  - (3) D-lysergic acid
  - (4) Ergotamine tartrate
  - (5) Diethyl malonate
  - (6) Malonic acid
  - (7) Ethyl malonate
  - (8) Barbituric acid
  - (9) Piperidine
  - (10) N-acetylanthranilic acid
  - (11) Pyrrolidine
  - (12) Phenylacetic acid
  - (13) Anthranilic acid
  - (14) Morpholine
  - (15) Ephedrine
  - (16) Pseudoephedrine or norpseudoephedrine
  - (17) Phenylpropanolamine
  - (18) Acetic anhydride
  - (19) Anthranilic acid, its esters and its salts
  - (20) Benzaldehyde
  - (21) Benzyl chloride
  - (22) Benzyl cyanide
  - (23) Ergonovine and its salts
  - (24) Hydriodic acid
  - (25) Isosafrole
  - (26) 3,4-methylenedioxyphenyl-2-propanone
  - (27) N-ethylephedrine, its salts, optical isomers, and salts of optical isomers

- (28) N-ethylpseudoephedrine, its salts, optical isomers, and salts of optical isomers
- (29) N-methylephedrine, its salts, optical isomers, and salts of optical isomers
- (30) N-methylpseudoephedrine, its salts, optical isomers, and salts of optical isomers
- (31) Nitroethane
- (32) 1-phenyl-1-chloro-2-methylaminopropanone (chlorephedrine, chloropseudoephedrine), their salts, optical isomers, and salts of optical isomers
- (33) Phenyl-2-propanone
- (34) Piperonal
- (35) Propionic anhydride
- (36) Safrole
- (37) Thionylchloride
- B. (1) Before selling, transferring, or otherwise furnishing to a person in this state a precursor substance designated in Subsection A of this Section, a manufacturer, wholesaler, retailer, or other person shall obtain from the buyer or recipient not representing a business the following information:
  - (a) The recipient's driver's license number or other personal identification certificate number, date of birth, and residential or mailing address, other than post office box number. This information shall be obtained from a driver's license or other personal identification card issued by the Department of Public Safety and Corrections that contains a photograph of the recipient;
  - (b) The year, state, and number of the motor vehicle license of the motor vehicle owned or operated by the recipient;
  - (c) A complete description of how the substance is to be used; and
  - (d) The recipient's signature.
  - (2) Before selling, transferring, or otherwise furnishing to a person in this state a precursor substance designated in Subsection A of this Section, a manufacturer, wholesaler, retailer, or other person shall obtain from the buyer or recipient representing a business the following information:
    - (a) A letter of authorization from the business that includes the business license or comptroller tax identification number, address, area code, and telephone number and a complete description of how the substance is to be used; and
    - (b) The signature of the recipient.
  - (3) For any recipient, the seller, manufacturer, or retailer shall sign as a witness to the signature and identification of the recipient.
- C. Except as provided by Subsection E of this Section, a manufacturer, wholesaler, retailer, or other person who sells, transfers, or otherwise furnishes to a person in this state a precursor substance designated in Subsection A of this Section shall, at least twenty-one days before the delivery of the substance, submit a report of the transaction on a form obtained from the deputy secretary that includes the information required by Subsection B of this Section.
- D. The deputy secretary shall supply to a manufacturer, wholesaler, retailer, or other person who sells, transfers, or otherwise furnishes a precursor substance subject to Subsection A of this Section a form for the submission of:
  - (1) The report required by Subsection C of this Section;
  - (2) The name and measured amount of the precursor substance delivered; and
  - (3) Any other information required by the deputy secretary.
- E. The deputy secretary shall require a manufacturer, wholesaler, retailer, or other person to submit a comprehensive monthly report instead of the report required by Subsection C of this Section if the deputy secretary determines either of the following:
  - (1) That there is a pattern of regular supply and purchase of the substance between the furnisher and the recipient; or
  - (2) That the recipient has established a record of utilization of the substance solely for a lawful purpose.
- F. A manufacturer, wholesaler, retailer, or other person who received from a source outside this state a substance designated in Subsection A of this Section or who discovers a loss or theft of a substance designated in Subsection A of this Section shall submit a report of the transaction to the deputy secretary in accordance with rules adopted pursuant to administrative procedure, and shall include in the report any difference between the amount of the substance actually received and the amount of the substance shipped according to the shipping statement or invoice or the amount of the loss or theft.
- G. A report required under Subsection F of this Section shall:
  - (1) Be made not later than the third day after the date that the manufacturer, wholesaler, retailer, or other person learns of the discrepancy, loss, or theft.
  - (2) If the discrepancy, loss, or theft occurred during a shipment of the substance, include the name of the common carrier or person who transported the substance and the date that the substance was shipped.
- H. The provisions of this Section shall not apply to the sale or transfer of a nonnarcotic product that includes a precursor substance listed in Subsection A of this Section, if the product may otherwise be sold lawfully with a

prescription or over the counter without a prescription under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or a rule adopted thereunder.

I. Any person who violates the provisions of this Section shall be imprisoned with or without hard labor for not more than one year, and in addition may be fined not more than one thousand dollars.

(Section added by Act 374 of the 1989 Regular Session; amended by Act 994 of the 1993 Regular Session; Act 206 of the 2018 Regular Session)

### §977. Order forms

Controlled dangerous substances in Schedules I and II shall be distributed only pursuant to an order form. (Section amended by Act 786 of the 1978 Regular Session; Act 834 of the 2006 Regular Session)

### §978. Prescriptions

- A. Except when dispensed or administered directly by a medical practitioner or administered by a person authorized to administer by such practitioner, other than a pharmacist, to an ultimate user, no controlled dangerous substance included in Schedule II, which is a prescription drug as determined under the Louisiana Revised Statutes, of 1950, may be dispensed or administered without either the written prescription of a practitioner, or an electronic prescription order as provided by federal law or regulation, except that in emergency situations, as prescribed by the board by regulation, such drug may be dispensed or administered upon oral prescription reduced promptly to writing and filed by the pharmacist. Prescriptions shall be retained in conformity with the requirements of R.S. 40:976. No prescription for a Schedule II substance may be refilled nor may such prescription be filled more than ninety days after the date of the prescription. The pharmacist filling a prescription for a Schedule II substance may, upon request of the patient, dispense the prescribed substance in an amount less than the full quantity prescribed in accordance with 21 U.S.C. 829.
- B. Except when dispensed or administered directly by a practitioner or administered by a person authorized to administer by such practitioner, other than a pharmacist, to an ultimate user, no controlled dangerous substance included in Schedule III and IV which is a prescription drug as determined under the Louisiana Revised Statutes may be dispensed or administered without either a written prescription, an oral prescription, or an electronic prescription order as provided by federal law or regulation. Such prescription may not be filled or refilled more than six months after the date thereof or refilled more than five times after the date of the prescription, unless renewed by the practitioner.
- C. No controlled dangerous substance included in Schedule V may be distributed, administered or dispensed other than for a medical purpose by prescription of a licensed practitioner or as otherwise permitted by the provisions of this Part. However, nothing contained in this Subsection shall prohibit a practitioner from delegating the authority to administer controlled dangerous substances in Schedule V to a person authorized by such practitioner.
- D. Notwithstanding the requirements of this Section, a prescription for a controlled substance listed in Schedule II, III, IV, or V may be generated, signed, transmitted, and received in electronic form, but only in conformance with the federal rules established by the United States Drug Enforcement Administration at 21 CFR 1311.
- E. (1) The pharmacist shall not dispense more than a ten-day supply at a dosage not to exceed the United States Food and Drug Administration's approved labeling for the medication if the prescriber for such medication is not licensed by the state of Louisiana, and the medication is an opioid derivative Schedule II or an opioid derivative Schedule III controlled dangerous substance. The dispensing pharmacist shall notify the prescriber of the supply dispensed and the cancellation of the remainder of the prescription.
  - (2) Within sixty days of the dispensing of a medication pursuant to Paragraph (1) of this Subsection, such a medication shall not be dispensed again for the individual by a prescriber not licensed by the state of Louisiana.
  - (3) The provisions of this Subsection shall not apply if either of the following apply:
    - (a) The prescription monitoring information from the state of the prescriber may be viewed by the dispensing pharmacist.
    - (b) The prescriber includes on the prescription a diagnosis of cancer or terminal illness.
- F. (1) A prescriber or his delegate shall access and review the patient's record in the prescription monitoring program established in R.S. 40:1001 et seq. prior to initially prescribing any opioid to a patient and shall access the prescription monitoring program and review the patient's record at least every ninety days if the patient's course of treatment continues for more than ninety days. The requirement established in this Subsection shall not apply in the following instances:
  - (a) The drug is prescribed or administered to a hospice patient or to any other patient who has been diagnosed as terminally ill.
  - (b) The drug is prescribed or administered for the treatment of cancer-related chronic or intractable pain.
  - (c) The drug is ordered or administered to a patient being treated in a hospital.
  - (d) The prescription monitoring program is inaccessible or not functioning properly due to an internal or

- external electronic issue. However, the prescriber or his delegate shall check the prescription monitoring program once electronic accessibility has been restored and note the cause for the delay in the patient's chart.
- (e) No more than a single seven-day supply of the drug is prescribed or administered to a patient.
- (2) The provisions of this Subsection shall be enforced by the health profession licensing board that regulates the prescriber. Each health profession licensing board that regulates prescribers shall promulgate rules and regulations in accordance with the <u>Administrative Procedure Act</u> to comply with the mandate in this Subsection. If a health profession licensing board becomes aware of a prescriber's first failure to comply with this Subsection, as verified by the data of the prescription monitoring program, the board shall notify the prescriber of the relevant statutory requirements and inform the prescriber of the need to correct or amend his prescribing practices to comply with the provisions of this Subsection. If a health profession licensing board becomes aware of a second or subsequent failure to comply with this Subsection, as verified by the data of the prescription monitoring program, the board shall treat the notification as a complaint against the licensee, but shall not consider such notice as evidence of deviation from standard of care.
- (3) The provisions of this Subsection shall not apply to individuals licensed by the Louisiana Board of Veterinary Medicine.
- G. (1) (a) Except as provided in Paragraph (2) of this Subsection, when issuing a first-time opioid prescription for outpatient use to an adult patient with an acute condition, a medical practitioner shall not issue a prescription for more than a seven-day supply.
  - (b) Except as provided in Paragraph (2) of this Subsection, a medical practitioner shall not issue a prescription for an opioid to a minor for more than a seven-day supply at any time and shall discuss with a parent, tutor, or guardian of the minor the risks associated with opioid use and the reasons why the prescription is necessary.
  - (2) If, in the professional medical judgment of a medical practitioner, more than a seven-day supply of an opioid is required to treat the adult or minor patient's acute medical condition or is necessary for the treatment of chronic pain management, pain associated with a cancer diagnosis, or for palliative care, the practitioner may issue a prescription for the quantity needed to treat the patient's acute medical condition or pain. The condition triggering the prescription of an opioid for more than a seven-day supply shall be documented in the patient's medical record and the practitioner shall indicate that a nonopioid alternative was not appropriate to address the medical condition. The medical practitioner shall indicate on the prescription that more than a seven-day supply of the opioid is medically necessary.
  - (3) This Subsection shall not apply to medications designed for the treatment of substance abuse or opioid dependence.
- H. (1) Prior to issuing a prescription for an opioid, a medical practitioner shall do both of the following:
  - (a) Consult with the patient regarding the quantity of the opioid and the patient's option to fill the prescription in a lesser quantity.
  - (b) Inform the patient of the risks associated with the opioid prescribed.
  - (2) (a) A pharmacist filling a prescription for an opioid may dispense the prescribed substance in an amount less than the recommended full quantity indicated on the prescription if requested by the patient and the prescription complies with the provisions of this Section. The patient may request that the pharmacist fill an additional amount not to exceed the remaining prescribed quantity in accordance with 21 U.S.C. 829.
    - (b) If the dispensed amount is less than the recommended full quantity, the pharmacist or a designee shall ensure that the actual dispensed amount is accurately recorded in the prescription monitoring program. The pharmacist or a designee shall also, within seven days, make a notation in the interoperable electronic health record of the patient if the pharmacist has access to the record.
    - (c) Nothing in this Subsection shall be interpreted to conflict with or supersede any other requirement established in this Section for a prescription of a controlled dangerous substance or any requirement or conditions for drug substitutions established by law.
- I. The transfer between pharmacies of a prescription or prescription information for controlled substances is permissible in conformance with 21 CFR Part 1306.

(Section amended by Act 155 of the 2011 Regular Session; Act 865 of the 2014 Regular Session; Act 189 of the 2015 Regular Session; Act 192 of the 2016 Regular Session; Acts 76 and 82 of the 2017 Regular Session; Acts 32, 206, 219 and 405 of the 2018 Regular Session; Act 426 of the 2019 Regular Session; Act 205 of the 2024 Regular Session)

## §978.1. Naloxone; first responder; prescription; administration to third party; limitation of liability

- A. For the purposes of this Section, the following definitions apply:
  - (1) "First responder" means any of the following:

- (a) A peace officer as defined in R.S. 40:2402.
- (b) A firefighter regularly employed by a fire department of any municipality, parish, or fire protection district of the state of Louisiana, or any volunteer fireman of the state of Louisiana.
- (c) An EMS practitioner as defined in R.S. 40:1131.
- (2) "Law enforcement agency" means an agency of a federally recognized Indian tribe or band or a state or political subdivision of a state, whose purpose is the detection and prevention of crime and enforcement of laws or ordinances.
- (3) "Opioid-related drug overdose" means a condition including extreme physical illness, decreased level of consciousness, respiratory depression, coma, or the ceasing of respiratory or circulatory function resulting from the consumption or use of an opioid, or another substance with which an opioid was combined.
- B. A first responder may receive a prescription for naloxone or another opioid antagonist, maintain the naloxone or other opioid antagonist in the first responder's possession, and administer the naloxone or other opioid antagonist to any individual who is undergoing or who is believed to be undergoing an opioid-related drug overdose.
- C. (1) Before receiving a prescription for naloxone or another opioid antagonist pursuant to this Section, a first responder shall complete the training necessary to safely and properly administer naloxone or another opioid antagonist to individuals who are undergoing or who are believed to be undergoing an opioid-related drug overdose. The training, at a minimum, shall cover all of the following:
  - (a) Techniques on how to recognize symptoms of an opioid-related overdose.
  - (b) Standards and procedures for the storage and administration of naloxone or another opioid antagonist.
  - (c) Emergency follow-up procedures.
  - (2) A first responder shall keep a record of each instance in which the first responder administers naloxone or another opioid antagonist to an individual who is undergoing or who is believed to be undergoing an opioid-related drug overdose.
- D. A law enforcement agency or fire department may enter into a written agreement to affiliate with an ambulance service provider or a physician for all of the following purposes:
  - (1) Obtaining a supply of naloxone or another opioid antagonist.
  - (2) Allowing law enforcement officers and firefighters to obtain the training necessary to safely and properly administer naloxone or another opioid antagonist to individuals who are undergoing or who are believed to be undergoing an opioid-related drug overdose.
- E. A first responder who, reasonably believing another person to be undergoing an opioid-related drug overdose, administers naloxone or another opioid antagonist to that person shall be immune from civil liability, criminal prosecution, or disciplinary or other adverse action under any professional licensing statute for any outcomes resulting from the administration of the naloxone or another opioid antagonist to that person, unless personal injury results from the gross negligence or willful or wanton misconduct of the first responder administering the drug.
- F. The deputy secretary of public safety services of the Department of Public Safety and Corrections shall develop and promulgate, in accordance with the <a href="Administrative Procedure Act">Act</a>, a set of best practices for use by a fire department or law enforcement agency in the administration and enforcement of this Section including but not limited to the training necessary to safely and properly administer naloxone or another opioid antagonist to individuals who are undergoing or who are believed to be undergoing an opioid-related drug overdose, the standards and procedures for the storage and administration of naloxone or another opioid antagonist, and emergency follow-up procedures.

(Section added by Act 253 of the 2014 Regular Session; amended by Act 206 of the 2018 Regular Session)

## §978.2. Naloxone; prescription; dispensing; administration by third party; limitation of liability

- A. A licensed medical practitioner may, directly or by standing order, prescribe or dispense the drug naloxone or another opioid antagonist without having examined the individual to whom it may be administered if both of the following conditions are met:
  - (1) The licensed medical practitioner provides the individual receiving and administering the naloxone or other opioid antagonist all training required by the department for the safe and proper administration of naloxone or another opioid antagonist to individuals who are undergoing or who are believed to be undergoing an opioid-related drug overdose. The training, at a minimum, shall address all of the following:
    - (a) Techniques on how to recognize signs of an opioid-related overdose.
    - (b) Standards and procedures for the storage and administration of naloxone or another opioid antagonist.
    - (c) Emergency follow-up procedure including the requirement to summon emergency services either immediately before or immediately after administering the naloxone or other opioid antagonist to an individual apparently experiencing an opioid-related overdose.

- (2) The naloxone or other opioid antagonist is prescribed or dispensed in such a manner that it shall be administered through a device approved for this purpose by the United States Food and Drug Administration.
- B. A licensed medical practitioner who, in good faith, prescribes or dispense naloxone or another opioid antagonist pursuant to Subsection A of this Section shall not, as a result of any act or omission, be subject to civil liability, criminal prosecution, or disciplinary or other adverse action under any professional licensing statute.
- C. (1) (a) A licensed pharmacist shall dispense naloxone or another opioid antagonist prescribed, directly or by standing order, by a licensed medical practitioner pursuant to this Section.
  - (b) A licensed pharmacist may dispense naloxone or another opioid antagonist pursuant to a nonpatient-specific standing order as provided for in rules promulgated by the Louisiana Board of Pharmacy.
  - (2) A licensed pharmacist who, in good faith, dispenses naloxone or another opioid antagonist pursuant to this Subsection shall not, as a result of any act or omission, be subject to civil liability, criminal prosecution, or disciplinary or other adverse action under any professional licensing statute.
- D. Notwithstanding any other provision of law or regulation, a person or organization acting pursuant to a standing order issued by a healthcare professional who is authorized to prescribe naloxone or another opioid antagonist may store naloxone or another opioid antagonist and may dispense naloxone or another opioid antagonist if such activities are performed without charge or compensation.
- E. Notwithstanding any other provision of law or regulation, any person may lawfully possess naloxone or another opioid antagonist.
- F. A person acting in good faith who, pursuant to the provisions of this Section, receives and administers naloxone or another opioid antagonist to a person reasonably believed to be undergoing an opioid-related drug overdose shall be immune from criminal and civil liability for the administration, unless personal injury results from the gross negligence or willful or wanton misconduct in the administration of the drug.
- G. The department shall develop and promulgate a set of best practices for use by a licensed medical practitioner pursuant to this Section including but not limited to the training necessary to safely and properly administer naloxone or another opioid antagonist to individuals who are undergoing or who are believed to be undergoing an opioid-related drug overdose, the standards and procedures for the storage and administration of naloxone or another opioid antagonist, and emergency follow-up procedures.
- H. For the purposes of this Section the following definitions apply:
  - (1) "Department" means the Department of Health.
  - (2) "Licensed medical practitioner" means a physician or other healthcare practitioner licensed, certified, registered, or otherwise authorized to perform specified healthcare services consistent with state law.
  - (3) "Opioid-related drug overdose" means a condition including extreme physical illness, decreased level of consciousness, respiratory depression, coma, or the ceasing of respiratory or circulatory function resulting from the consumption or use of an opioid, or another substance with which an opioid was combined.

(Section added by Act 192 of the 2015 Regular Session; amended by Act 370 of the 2016 Regular Session)

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### §984. Powers of enforcement personnel

The Louisiana Board of Pharmacy's authorized employees may:

- (1) Carry firearms;
- (2) Execute and serve search warrants, arrest warrants, administrative inspection warrants, subpoenas, and summonses issued under the authority of this state;
- (3) Make arrests without warrant for any offense under this Part on the same basis as provided in <u>Code of Criminal Procedure Article 213</u>; and
- (4) Make seizures of property pursuant to the authority granted under the provisions of this Part. (Section amended by Act 786 of the 1978 Regular Session; Act 834 of the 2006 Regular Session)

### §985. Search warrants

A search warrant relating to offenses involving controlled dangerous substances may be authorized to be served at any time of the day or night if the judge or magistrate issuing the warrant is satisfied that there is probable cause to believe that grounds exist for the warrant.

### §986. Administrative inspections and warrants

- A. Issuance and execution of administrative inspection warrants shall be as follows:
  - (1) Any judge of a state court of record, or any state magistrate of any court of record may, within his jurisdiction, and upon proper oath or affirmation after being satisfied there is probable cause to believe that

- legal grounds exist for the issuance of such warrant, issue warrants for the purpose of conducting administrative inspections authorized by this Part or regulations thereunder, and may authorize seizure of property related to such inspections.
- (2) A warrant shall issue only upon an affidavit of any law enforcement officer or employee designated in R.S. 40:984 having knowledge of the facts alleged, sworn to before a judge or magistrate of any court of record and establishing the grounds for issuing the warrant. If the judge or magistrate of any court of record is satisfied that grounds for the application exist or that there is probable cause to believe they exist, he shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of such inspection, and, where appropriate, the type of property to be inspected, if any. The warrant shall also identify the item or types of property to be seized, if any. The warrant shall be directed to a person authorized by R.S. 40:984 to execute it. The warrant shall state the grounds for its issuance and the name of the person or persons whose affidavit has been taken in support thereof. It shall command the person to whom it is directed to inspect the area, premises, building, or conveyance identified for the purposes specified, and, where appropriate, shall also direct the seizure of the property specified. The warrant shall direct that it be served during normal business hours. It shall designate the judge or magistrate of any court of record to whom it shall be returned.
- (3) A search warrant issued pursuant to this Section shall be executed and returned within ten days of its date. If property is seized pursuant to a warrant, the person executing the warrant shall give to the person from whom or from whose premises the property was taken a copy of the warrant and a receipt for the property taken. The return of the warrant shall be made promptly and shall be accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken. The judge or magistrate of any court of record, upon request, shall deliver a copy of the inventory to the person from whom or from whose premises the property was taken and to the applicant for the warrant.
- (4) The judge or magistrate of any court of record who has issued a warrant under this Section shall attach to the warrant a copy of the return and all papers filed in connection therewith and shall file them with the clerk of the state court for the judicial district in which the inspection was made.
- B. The Louisiana Board of Pharmacy is authorized to make administrative inspections of controlled premises in accordance with the following provisions:
  - (1) For purposes of this Section only, "controlled premises" means all of the following:
    - (a) Places where persons licensed or exempted from licensing requirements under this Part are required to keep records.
    - (b) Places including factories, warehouses, establishments, and conveyances where persons licensed or exempted from licensing requirements under this Part are permitted to possess, manufacture, compound, process, sell, deliver, or otherwise dispose of any controlled dangerous substance.
  - (2) When so authorized by an administrative inspection warrant issued pursuant to Subsection A of this Section a law enforcement officer or an employee as designated in R.S. 40:984, upon presenting the warrant and appropriate credentials to the owner, operator, or agent in charge, shall have the right to enter controlled premises for the purpose of conducting such an administrative inspection.
  - (3) When so authorized by an administrative inspection warrant, a law enforcement officer or an employee as designated in R.S. 40:984 shall have the right:
    - (a) To inspect and copy records required by this Part to be kept;
    - (b) To inspect, within reasonable limits and in a reasonable manner, the controlled premises and all pertinent equipment, finished and unfinished material, containers and labeling found therein, and except as provided in Paragraph (B)(5) of this Section, all other things therein including records, files, papers, processes, controls, and facilities subject to regulation and control by the provisions of this Part or by regulations promulgated by the Louisiana Board of Pharmacy; and
    - (c) To inventory any stock of any controlled dangerous substance therein and obtain samples of any such substance.
  - (4) This Section shall not be construed to prevent the inspection without a warrant of books and records pursuant to an administrative subpoena issued in accordance with this Section nor shall this Section be construed to prevent entries and administrative inspections including seizures of property without a warrant:
    - (a) With the written consent of the owner, operator, or agent in charge of the controlled premises; or
    - (b) In situations involving inspection of conveyances where there is probable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant.
  - (5) Except when the owner, operator, or agent in charge of the controlled premises so consents in writing, no inspection authorized by this Section shall extend to any of the following:
    - (a) Financial data.
    - (b) Sales data other than shipment data.

(c) Pricing data.

(Section amended by Act 786 of the 1978 Regular Session; Act 834 of the 2006 Regular Session; Act 206 of the 2018 Regular Session)

### §987. Injunctions

Any district court of this state shall have jurisdiction in proceedings in accordance with the rules of such courts to enjoin violations of this Part and in accordance with the <u>Code of Civil Procedure</u> and other laws of this state. (Section amended by Act 206 of the 2018 Regular Session)

### §988. Cooperative arrangements; inspections

- A. The Louisiana Board of Pharmacy may cooperate with federal and other state agencies in discharging its responsibilities concerning dangerous substances. To this end, it is authorized to:
  - (1) Arrange for the exchange of information between governmental officials concerning the use and abuse of dangerous substances.
  - (2) Coordinate and cooperate in training programs on dangerous substance law enforcement at the local and state levels.
  - (3) Cooperate with the Federal Bureau of Narcotics and Dangerous Drugs by establishing a centralized unit which will receive, catalogue, file, and collect statistics, including records of drug dependent persons and other dangerous substance law offenders within the state, and make such information available for federal, state, and local law enforcement purposes.
  - (4) Conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled dangerous substances may be extracted.
- B. (1) Any other provision of this Part to the contrary notwithstanding, the inspections authorized or required by that law, insofar as pharmacists and pharmacies registered and licensed under the Louisiana Board of Pharmacy only are concerned, shall be conducted by the Louisiana Board of Pharmacy, through its duly authorized officers, members, inspectors, agents and representatives, insofar as pharmacists and pharmacies registered and licensed under the Louisiana Board of Pharmacy are concerned; and compliance with requirements involving security measures, inventories, records and reports required by that law and/or the regulations promulgated from time to time in connection therewith shall be administratively determined by the Louisiana Board of Pharmacy, insofar as pharmacists and pharmacies registered and licensed under the Louisiana Board of Pharmacy only are concerned.
  - (2) Any other provision of this Part to the contrary notwithstanding, the inspections authorized or required by that law, insofar as physicians licensed to practice medicine by the Louisiana State Board of Medical Examiners only are concerned, shall be conducted by the Louisiana State Board of Medical Examiners, through its duly authorized officers, members, inspectors, agents, and representatives, insofar as physicians licensed to practice medicine by the Louisiana State Board of Medical Examiners are concerned. Compliance with requirements involving security measures, inventories, records, and reports required by that law or the regulations promulgated in connection therewith, or both, shall be administratively determined by the Louisiana State Board of Medical Examiners insofar as physicians licensed to practice medicine by the Louisiana State Board of Medical Examiners only are concerned.
- C. Any other provision of this Part to the contrary notwithstanding, the inspections authorized or required by that law, insofar as persons licensed by the Louisiana Department of Health including dentists, veterinarians, scientific investigators, hospitals, or other persons licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled dangerous substance in the course of professional practice or research in this state, shall be conducted and furnished exclusively by the Louisiana Department of Health, through its duly authorized officers, members, inspectors, agents and representatives, insofar as dentists, veterinarians, scientific investigators, hospitals, or other persons licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled dangerous substance in the course of professional practice or research in this state registered and licensed under the Louisiana Department of Health are concerned; and compliance with requirements involving security measures, inventories, records and reports required by that law and/or the regulations promulgated from time to time in connection therewith shall be administratively determined by the Louisiana Department of Health.

(Section amended by Act 786 of the 1978 Regular Session; Act 834 of the 2006 Regular Session; Act 206 of the 2018 Regular Session)

## §989. Dangerous chemical substances; butyl nitrite, nitrous oxide, and amyl nitrite; use and transference; penalties

A. (1) It shall be unlawful for any person to inhale, ingest, use, or possess any compound, liquid, gas, or chemical

- which contains butyl nitrite, isobutyl nitrite, secondary butyl nitrite, tertiary butyl nitrite, and mixtures containing butyl nitrite, isobutyl nitrite, secondary butyl nitrite, or tertiary butyl nitrite.
- (2) It shall be unlawful for any person to inhale, ingest, use, or possess any compound, liquid, gas, or chemical which contains nitrous oxide, commonly known as "laughing gas" and any amyl nitrite, commonly known as "poppers" or "snappers".
- B. The provisions of Subsection A of this Section shall not apply to any of the following:
  - (1) The possession and use of these substances prescribed as part of the care or treatment of a disease, condition, or injury by a licensed medical or dental practitioner.
  - (2) The possession and use of these substances by a manufacturer as part of a manufacturing process or industrial operation.
  - (3) The possession, use, or sale of nitrous oxide as a propellant in food preparation for restaurant, food service, or houseware products.
  - (4) The possession, use, or sale of nitrous oxide for automotive purposes.
- C. It shall be unlawful for any person, entity, business, or corporation to produce, manufacture, possess, buy, sell, or otherwise transfer any substance specified in Subsection A of this Section or otherwise violate the provisions of Subsection A.
- D. Whoever violates the provisions of this Section shall be fined not more than two thousand five hundred dollars or imprisoned with or without hard labor for not more than one year, or both.
- E. Any person who violates any of the provisions of this Section may, in the discretion of the trial judge, be required to participate in an approved drug rehabilitation program, as a condition of probation.
- F. (1) The office of alcohol and tobacco control may conduct any investigation as necessary to regulate and enforce the provisions of this Section.
  - (2) The provisions of this Subsection shall not prohibit a law enforcement agency of the state or its political subdivisions with appropriate jurisdiction from enforcing the provisions of this Section.
- G. The office of alcohol and tobacco control shall promulgate rules and regulations in accordance with the <u>Administrative Procedure Act</u> to provide for the regulation and enforcement of this Section.

(Section added by Act 777 of the 1988 Regular Session; amended by Act 933 of the 1992 Regular Session; Act 500 of the 1993 Regular Session; Act 248 of the 2024 Regular Session)

## §989.1. Unlawful production, manufacture, distribution, or possession of hallucinogenic plants; exceptions

- A. (1) It shall be unlawful for any person knowingly or intentionally to produce, manufacture, distribute, or possess with intent to produce, manufacture, or distribute a material, compound, mixture, or preparation intended for human consumption which contains a hallucinogenic plant.
  - (2) Whoever violates the provisions of this Subsection shall be sentenced to a term of imprisonment with or without hard labor for not less than two years nor more than ten years and may, in addition, be sentenced to pay a fine of not more than twenty thousand dollars.
- B. (1) It shall be unlawful for any person knowingly or intentionally to possess a material, compound, mixture, or preparation intended for human consumption which contains a hallucinogenic plant.
  - (2) Any person who violates the provisions of this Subsection shall be sentenced to a term of imprisonment with or without hard labor for not more than five years and may, in addition, be sentenced to pay a fine of not more than five thousand dollars.
- C. For the purposes of this Section:
  - (1) "Distribute" means to sell, lease, rent, barter, trade, furnish, supply, or otherwise transfer in exchange for anything of value a material, compound, mixture, or preparation intended for human consumption which contains a hallucinogenic plant.
  - (2) "Hallucinogenic plant" means any part or portion of any of the following:
    - (a) Brugmansia arborea.
    - (b) Amanita muscaria.
    - (c) Conocybe spp.
    - (d) Panaeolus spp.
    - (e) Psilocybe spp.
    - (f) Stropharia spp.
    - (g) Vinca rosea.
    - (h) Ipomoea violacea.
    - (i) Datura spp.
    - (j) Pancreatium trianthum.
    - (k) Kaempferia galangal.
    - (l) Olmedioperebea sclerophylla.

- (m) Mesembryanthemum spp.
- (n) Virola spp.
- (o) Anadenanthera peregrina.
- (p) Anadenanthera colubrine.
- (q) Erythina spp.
- (r) Genista canariensis.
- (s) Mimosa hostilis.
- (t) Rhynchosia spp.
- (u) Sophora secundiflora.
- (v) Peganum harmala.
- (w) Banisteriopsis spp.
- (x) Tetrapteris methystica.
- (y) Heimia salicfolia.
- (z) Tabernanthe iboga.
- (aa) Prestonia amazonica.
- (bb) Lagoehilus inebrians.
- (cc) Rivea corymbosa.
- (dd) Salvia divinorum.
- (ee) Atropa belladonna.
- (ff) Hyoscyamus niger.
- (gg) Mandragora officinarum.
- (hh) Brunfelsia spp.
- (ii) Methysticodendron anesianum.
- (jj) Latua pubiflora.
- (kk) Calea Zacatechichi.
- (ll) Physalis subglabrata.
- (mm) Solanum carolinense.
- (nn) Amanita pantherina.
- (3) "Homeopathic drug" means any drug labeled as being homeopathic which is listed in the Homeopathic Pharmacopeia of the United States, an addendum to it, or its supplements. The potencies of homeopathic drugs are specified in terms of dilution. Homeopathic drug products must contain diluents commonly used in homeopathic pharmaceutics. Drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not homeopathic drug products.
- (4) "Manufacture" means the production, preparation, propagation, compounding, or processing of a material, compound, mixture, or preparation intended for human consumption which contains a hallucinogenic plant either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Manufacturer includes any person who packages, repackages, or labels any container holding a material, compound, mixture, or preparation intended for human consumption which contains a hallucinogenic plant.
- (5) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a hallucinogenic plant.
- D. The provisions of this Section shall not apply to the possession, planting, cultivation, growing, or harvesting of a hallucinogenic plant strictly for aesthetic, landscaping, or decorative purposes.
- E. The provisions of this Section shall not apply to any dosage form which is legally obtainable from a retail establishment without a prescription and is recognized by the Federal Food and Drug Administration as a homeopathic drug.
- F. The provisions of this Section shall not apply to any dosage form which is labeled as a dietary supplement and is manufactured in compliance with the requirements of Sections 402(g)(2), 415, and 761 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(g)(2), 350d, and 379aa-1).

(Section added by Act 159 of the 2005 Regular Session; amended by Act 373 of the 2015 Regular Session; Act 206 of the 2018 Regular Session; Act 201 of the 2023 Regular Session)

## §989.2. Unlawful production, manufacturing, distribution, or possession of prohibited plant products; exceptions

- A. (1) It shall be unlawful for any person knowingly or intentionally to produce, manufacture, distribute, or possess with intent to produce, manufacture, or distribute a material, compound, mixture, or preparation which contains a prohibited plant and which meets any of the following criteria:
  - (a) It is intended to be placed in the oral or nasal cavity.
  - (b) It is prepared in such a manner as to be suitable for smoking in a pipe or cigarette, or other device.

- (c) It is to be burned and inhaled or exhaled in any manner or in any form.
- (2) Whoever violates the provisions of this Subsection shall be sentenced to a term of imprisonment with or without hard labor for not more than five years and may, in addition, be sentenced to pay a fine of not more than ten thousand dollars.
- B. (1) It shall be unlawful for any person knowingly or intentionally to possess material, compound, mixture, or preparation which contains a prohibited plant and which is intended to be placed in the oral or nasal cavity, is prepared in such a manner as to be suitable for smoking in a pipe or cigarette, or is to be burned and inhaled or exhaled in any manner or in any form.
  - (2) Any person who violates the provisions of this Subsection shall be fined not more than five hundred dollars, imprisoned for not more than six months, or both.
- C. For the purposes of this Section:
  - (1) "Distribute" means to sell, barter, trade, furnish, supply, or otherwise transfer in exchange for anything of value a material, compound, mixture, or preparation which contains a prohibited plant.
  - (2) "Homeopathic drug" means any drug labeled as being homeopathic which is listed in the Homeopathic Pharmacopoeia of the United States, an addendum to it, or its supplements. The potencies of homeopathic drugs are specified in terms of dilution. Homeopathic drug products must contain diluents commonly used in homeopathic pharmaceutics. Drug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not homeopathic drug products.
  - (3) "Manufacture" means the production, preparation, propagation, compounding, or processing of a material, compound, mixture, or preparation which contains a prohibited plant either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Manufacturer includes any person who packages, repackages, or labels any container holding a material, compound, mixture, or preparation which contains a prohibited plant.
  - (4) "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a prohibited plant.
  - (5) "Prohibited plant" means any combination of any of the parts, leaves, stems, stalks, seeds, materials, compounds, salts, derivatives, mixtures, preparations, or any resin extracted from any part of the following plants:
    - (a) Artemisia vulgaris (Mugwort).
    - (b) Canavalia rosea (Bay bean).
    - (c) Leonotis leonurus (Lion's tail).
    - (d) Leonotis nepetifolia (Lion's ear).
    - (e) Leonurus sibiricus (Honeyweed).
    - (f) Nelumbo nucifera (Sacred Lotus).
    - (g) Nymphaea caerulea (Blue Lotus, Egyptian Lotus).
    - (h) Pedicularis densiflora (Indian warrior).
    - (i) Salvia divinorum.
    - (j) Scutellaria nana (Dwarf skullcap).
    - (k) Turnera diffusa (Damiana).
    - (l) Zornia latifolia.
- D. The provisions of this Section shall not apply to any dosage form which is legally obtainable from a retail establishment without a prescription and is recognized by the United States Food and Drug Administration as a homeopathic drug.
- E. The provisions of this Section shall not apply to the possession, planting, cultivation, growing, or harvesting of a prohibited plant strictly for aesthetic landscaping, or decorative purposes.
- F. The provisions of this Section shall not apply to any dosage form which is labeled as a dietary supplement and is manufactured in compliance with the requirements of Sections 402(g)(2), 415, and 761 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(g)(2), 350d, and 379aa-1).

(Section added by Act 565 of the 2010 Regular Session; amended by Act 373 of the 2015 Regular Session; Act 206 of the 2018 Regular Session)

### §989.3. Unlawful distribution of products containing Mitragyna speciosa to minors; penalties

- A. It shall be unlawful for any person to distribute any product containing Mitragyna speciosa to a minor.
- B. Whoever violates the provisions of this Subsection shall be fined not more than five hundred dollars or imprisoned for not more than six months, or both.

(Section added by Act 355 of the 2012 Regular Session)

### §989.4. Unlawful production, manufacturing, distribution, or possession of xylazine

A. (1) It shall be unlawful for any person to knowingly or intentionally produce, manufacture, distribute, or possess

- with intent to produce, manufacture, or distribute xylazine.
- (2) Whoever violates the provisions of this Subsection shall be imprisoned, with or without hard labor, for not less than one year nor more than ten years and, in addition, may be required to pay a fine of not more than fifteen thousand dollars.
- B. (1) It shall be unlawful for any person to knowingly or intentionally possess xylazine.
  - (2) Whoever violates the provisions of this Subsection shall be imprisoned for not more than six months and, in addition, may be required to pay a fine of not more than five hundred dollars.
- C. The provisions of this Section shall not apply to the following:
  - (1) The production, manufacturing, distribution, or possession of xylazine in the course of a legitimate veterinary practice.
  - (2) The production, manufacturing, distribution, or possession of a xylazine bulk chemical for pharmaceutical compounding by a licensed pharmacist or veterinarian.
  - (3) The possession of xylazine pursuant to a valid prescription from a licensed veterinarian.
- D. As used in this Section, "xylazine" means xylazine and any salt, sulfate, isomer, homologue, analogue, or other preparation of xylazine, and any salt, isomer, compound, derivative, precursor, homologue, analogue, or other preparation thereof that is substantially chemically equivalent or identical to xylazine.

(Section added by Act 183 of the 2023 Regular Session)

\* \* \*

### §992. Education and research

- A. The Louisiana Board of Pharmacy is authorized to carry out educational programs designed to prevent and deter misuse and abuse of controlled dangerous substances. In connection with such programs, it is authorized to:
  - (1) Promote better recognition of the problems of misuse and abuse of controlled dangerous substances within the regulated industry and among interested groups and organizations.
  - (2) Assist the regulated industry and interested groups and organizations in contributing to the reduction of misuse and abuse of controlled dangerous substances.
  - (3) Consult with interested groups and organizations to aid them in solving administrative and organizational problems.
  - (4) Evaluate procedures, projects, techniques, and controls conducted or proposed as part of educational programs on misuse and abuse of controlled dangerous substances.
  - (5) Disseminate to the industry and the general public the results of research on misuse and abuse of controlled dangerous substances to promote a better public understanding of what problems exist and what can be done to combat them.
  - (6) Assist in the education and training of state and local law enforcement officials in their efforts to control misuse and abuse of controlled dangerous substances.
- B. The Louisiana Board of Pharmacy is authorized to encourage research on misuse and abuse of controlled dangerous substances. In connection with such research and in furtherance of the enforcement of this Part, it is authorized to:
  - (1) Establish methods to assess accurately the effects of controlled dangerous substances and to identify and characterize controlled dangerous substances with potential for abuse.
  - (2) Make studies and undertake programs of research to:
    - (a) Develop new or improved approaches, techniques, systems, equipment and devices to strengthen the enforcement of this Part.
    - (b) Determine patterns of misuse and abuse of controlled dangerous substances and the social effects thereof.
    - (c) Improve methods for preventing, predicting, understanding, and dealing with the misuse and abuse of controlled dangerous substances.
  - (3) Enter into contracts with public agencies or institutions of higher education, for the purpose of conducting research, demonstrations, or special projects which bear directly on misuse and abuse of controlled dangerous substances.
- C. The Louisiana Board of Pharmacy may authorize persons engaged in research on the use and effects of dangerous substances to withhold the names and other identifying characteristics of persons who are the subjects of such research. Persons who obtain this authorization shall not be compelled, in any civil, criminal, administrative, legislative, or other proceeding to identify the subjects of research for which authorization was obtained.
- D. The Louisiana Board of Pharmacy may authorize the possession and distribution of controlled dangerous substances by persons engaged in research in accordance with rules promulgated by the department. Persons who obtained this authorization shall be exempt from state prosecution for possession and distribution of dangerous substances to the extent authorized by the Louisiana Board of Pharmacy.

E. The Louisiana Board of Pharmacy, with the concurrence and under the supervision and control of the chief law enforcement officer of the jurisdiction wherein the program is conducted, may authorize the possession and exhibition for educational purposes only of controlled dangerous substances by persons employed by local and state law enforcement agencies engaged in educational programs in accordance with rules promulgated by the Louisiana Board of Pharmacy. Persons acting pursuant to this authorization shall be exempt from state and local prosecution for the possession and distribution of dangerous substances to the extent authorized by the Louisiana Board of Pharmacy. The Louisiana Board of Pharmacy shall coordinate and evaluate the training programs of the various law enforcement agencies to ensure compliance with the rules promulgated regulating the possession and exhibition of controlled dangerous substances for educational purposes.

(Section amended by Act 786 of the 1978 Regular Session; Act 218 of the 1984 Regular Session; Act 834 of the 2006 Regular Session; Act 206 of the 2018 Regular Session)

\* \* \*

### §995. Short title

This Part may be cited as the Uniform Controlled Dangerous Substances Law. (Section amended by Act 206 of the 2018 Regular Session)

[End of Part X]

### Part X-A. Prescription Monitoring Program

[This new Part X-A was created by Act 676 of the 2006 Regular Session, effective July 1, 2006. Subsequent amendments are noted herein.]

### §1001. Short title

This Section shall be known and may be cited as the "Prescription Monitoring Program Act."

### §1002. Purpose

The purpose of this Part is to authorize the development, implementation, operation, and evaluation of an electronic system for the monitoring of controlled substances and other drugs of concern that are dispensed in the state or dispensed to an address within the state. The goal of the program is to improve the state's ability to identify and inhibit the diversion of controlled substances and drugs in an efficient and cost-effective manner and in a manner that shall not impede the appropriate utilization of these drugs for legitimate medical purposes.

### §1003. Definitions

As used in this Part, the following terms shall have the meaning ascribed to them unless the context clearly indicates otherwise:

- (1) "Administer" or "administration" means the direct application of a drug to the body of a patient by injection, inhalation, ingestion, or any other means.
- (2) "Advisory council" means the entity established in R.S. 40:1005.
- (3) (a) "Audit trail information" means information submitted or produced regarding requests for prescription monitoring program data that the board or other individual as specified by this Part uses to help monitor compliance with this Part and other applicable statutes, rules or regulations.
  - (b) "Audit trail information" shall not include any information produced or requested by the Louisiana legislative auditor.
- (4) "Board" means the Louisiana Board of Pharmacy.
- (5) "Controlled substance" means any substance or drug defined, enumerated, or included in federal or state statute or rules, 21 CFR 1308.11-15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such regulations or statute. "Controlled substance" shall not include distilled spirits, wine, malt beverages, or tobacco.
- (6) "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.
- (7) "Dispenser" means a person authorized by this state to dispense or distribute to the ultimate user any controlled substance or drug monitored by the program, but shall not include any of the following:
  - (a) A pharmacy permitted by the board as a hospital pharmacy that dispenses or distributes any controlled substance or drug monitored by the program for the purposes of inpatient health care.
  - (b) A practitioner who dispenses or distributes no more than a single forty-eight hour supply of such controlled substance or drug to a patient prior to, or subsequent to, performing an actual procedure on that patient.
  - (c) A practitioner or other authorized person who administers such controlled substance or drug upon the lawful order of a practitioner.
  - (d) A wholesale distributor of such controlled substance or drug that is credentialed by the Louisiana State Board of Wholesale Drug Distributors.
- (8) "Distribute" or "distribution" means the delivery of a drug or device other than by administering or dispensing.
- (9) "Drug" means any of the following:
  - (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 disease 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.
  - (c) Any substance other than food intended to affect the structure or any function of the body of humans or other animals
- (10) "Drugs of concern" means drugs other than controlled substances as defined by rule which demonstrate a potential for abuse or whose use requires tracking for public health purposes.
- (11) "Patient" means the person or animal who is the ultimate user of a controlled substance or drug monitored by the program for whom a prescription is issued and for whom a controlled substance or drug is dispensed.
- (12) "Prescriber" means a licensed healthcare professional with prescriptive authority.
- (13) "Prescription monitoring information" means data submitted to and maintained by the prescription monitoring program.

- (14) "Prescription monitoring program" or "PMP" means the program established in R.S. 40:1004.
- (15) "Procedure" means any dental or medical practice or process described in the current year's version of the American Dental Association's <u>Current Dental Terminology</u> or the American Medical Association's <u>Code of Procedural Terminology</u>.

(Section amended by Act 241 of the 2017 Regular Session; Acts 146 and 206 of the 2018 Regular Session)

### §1004. Establishment of prescription monitoring program

- A. The board shall establish and maintain, in consultation with and upon the recommendation of the advisory council, an electronic system for the monitoring of controlled substances and drugs of concern dispensed in the state or dispensed to an address in the state.
- B. In conformity with the Louisiana Public Bid Law, <u>R.S. 38:2211</u> *et seq.*, the board may contract with a vendor to establish and maintain the electronic monitoring system pursuant to rules promulgated by the board.
- C. This Part shall not apply to any person licensed pursuant to R.S. 37:1511 et seq. (Section amended by Act 27 of the 2013 Regular Session)

### §1005. Prescription Monitoring Program Advisory Council

- A. The advisory council shall consist of the following members, each of whom may appoint a designee:
  - (1) The president of the Louisiana State Board of Medical Examiners.
  - (2) The president of the Louisiana State Board of Dentistry.
  - (3) The president of the Louisiana State Board of Nursing.
  - (4) The president of the Louisiana State Board of Optometry Examiners.
  - (5) The president of the Louisiana Academy of Physicians Assistants.
  - (6) The president of the Louisiana Board of Pharmacy.
  - (7) The superintendent of the Louisiana State Police.
  - (8) The administrator of the United States Drug Enforcement Administration.
  - (9) The speaker of the Louisiana House of Representatives.
  - (10) The president of the Louisiana Senate.
  - (11) The chairman of the House Committee on Health and Welfare.
  - (12) The chairman of the Senate Committee on Health and Welfare.
  - (13) The secretary of the Department of Health.
  - (14) The president of the Louisiana State Medical Society.
  - (15) The president of the Louisiana Dental Association.
  - (16) The president of the Louisiana Association of Nurse Practitioners.
  - (17) The president of the Optometry Association of Louisiana.
  - (18) The president of the Louisiana Pharmacists Association.
  - (19) The president of the Louisiana Independent Pharmacies Association.
  - (20) The president of the National Association of Chain Drug Stores.
  - (21) The president of the Louisiana Sheriffs' Association.
  - (22) The president of the Louisiana District Attorneys Association.
  - (23) The president of the Pharmaceutical Research and Manufacturers of America.
  - (24) The president of the Louisiana Academy of Medical Psychologists.
- B. The members of the advisory council shall serve at the pleasure of their respective appointing authorities, eleven of whom shall constitute a quorum for the transaction of all business. The members shall elect a chairman and vice chairman whose duties shall be established by the advisory council. The board shall fix a time and place for regular meetings of the advisory council, which shall meet at least once annually. The advisory council shall establish policies and procedures necessary to carry out its duties.
- C. The board shall seek, and the advisory council shall provide, information and advice regarding the development and operation of the electronic monitoring system, including but not limited to the following:
  - (1) Which controlled substances should be monitored.
  - (2) Which drugs of concerns demonstrate a potential for abuse and should be monitored.
  - (3) Design and implementation of educational courses identified in R.S. 40:1008.
  - (4) The methodology to be used for analysis and interpretation of prescription monitoring information.
  - (5) Design and implementation of a program evaluation component.
  - (6) Identification of potential additional members to the advisory council.
- D. The advisory council may conduct and its members may attend and participate in a meeting via electronic means in accordance with the provisions of R.S. 42.17.4.

(Section amended by Act 142 of the 2010 Regular Session; Act 206 of the 2018 Regular Session; Act 14 of the 2023 Regular Session)

### §1006. Reporting of prescription monitoring information

- A. Each dispenser shall submit to the board information regarding each prescription dispensed for a controlled substance or drug monitored by the program. The information submitted for each prescription shall include, at a minimum, data relative to the identification of the following elements of the transaction:
  - (1) Prescriber information.
  - (2) Patient information.
  - (3) Prescription information.
  - (4) Controlled substance or drug information.
  - (5) Dispenser information.
- B. Each dispenser shall submit the required information in accordance with transmission methods and frequency established by the board. Each eligible prescription transaction shall be reported no later than the next business day after the date of dispensing.
- C. The board may issue a waiver to a dispenser who is unable to submit prescription information by electronic means. The waiver shall state the format and frequency with which the dispenser shall submit the required information. The board may issue an exemption from the reporting requirement to a dispenser whose practice activities are inconsistent with the intent of the program. The board may rescind any previously issued exemption without the need for an informal or formal hearing.
- D. Any person or entity required to report information concerning prescriptions to the board or to its designated agent pursuant to the requirements of this Part shall not be liable to any person or entity for any claim of damages as a result of the act of reporting the information and no lawsuit may be predicated thereon. Any person or entity who submits report information in good faith containing prescription information that is not the subject of the PMP shall not be liable to any person or entity for any claim of damages and no lawsuit may be predicated thereon.
- E. The prescription monitoring program's agents, a dispenser, or a prescriber may report suspected violations of this Section or violations of any law to any local, state, out-of-state, or federal law enforcement agency, or the appropriate prosecutorial agency for further investigation or prosecution.
- F. No agent, dispenser, or prescriber who in good faith reports suspected violations as provided for in Subsection E of this Section shall be liable to any person or entity for any claim of damages as a result of the act of reporting the information, and no lawsuit may be predicated thereon.
- G. The board shall establish by rulemaking standards for the retention, archiving, and destruction of prescription monitoring information.

(Section amended by Acts 129 and 314 of the 2009 Regular Session; Act 488 of the 2010 Regular Session; Act 472 of the 2014 Regular Session; Act 189 of the 2016 Regular Session; Act 206 of the 2018 Regular Session)

### §1007. Access to prescription monitoring information and audit trail information

- A. Except as provided in Subsections C, D, E, F, G, H, and I of this Section, prescription monitoring information submitted to the board and audit trail information shall be protected health information, not subject to public or open records law, including but not limited to R.S. 44:1 et seq., and not subject to disclosure. Prescription monitoring information and audit trail information shall not be available for civil subpoena from the board nor shall such information be disclosed, discoverable, or compelled to be produced in any civil proceeding nor shall such records be deemed admissible as evidence in any civil proceeding for any reason. Notwithstanding this provision, law enforcement and professional licensing, certification, and regulatory agencies may utilize prescription monitoring information and audit trail information in the course of any investigation and subsequent criminal and administrative proceedings, but only in accordance with federal and state law and the requirements of this Part.
- B. The board shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained, as well as audit trail information, is not disclosed to persons or entities except as authorized or required in Subsections C through J of this Section.
- C. The board shall review the prescription monitoring information. If there is reasonable suspicion to believe a breach of professional or occupational standards may have occurred, the board shall notify the appropriate professional licensing agency with jurisdiction over prescribers or dispensers and shall provide prescription monitoring information required for an investigation.
- D. The board shall provide prescription monitoring information to public or private entities, whether located in or outside of the state, for public research, policy, or educational purposes, but only after removing information that identifies or could be reasonably be used to identify prescribers, dispensers, and individual patients or persons who received prescriptions from prescribers.
- E. The following persons may access prescription monitoring information at no cost and in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar protected health information under federal and state law and regulation:

- (1) Persons authorized to prescribe or dispense controlled substances or drugs of concern, or their delegates as defined by rule, for the purpose of providing medical or pharmaceutical care for their patients, or for verifying their prescriptions records.
- (2) Designated representatives from the professional licensing, certification, or regulatory agencies of this state or another state charged with administrative oversight of those professionals engaged in the prescribing or dispensing of controlled substances or other drugs of concern.
- (3) Designated representatives from the Louisiana Medicaid program regarding Medicaid program recipients.
- (4) Designated representatives of the board and any vendor or contractor establishing or maintaining the prescription monitoring program.
- (5) A medical examiner or coroner, or a delegate thereof, for the purpose of investigating an individual's death.
- (6) A licensed substance abuse addiction counselor providing services as part of a state-licensed substance abuse or addiction treatment program.
- (7) A probation or parole officer for the purpose of monitoring an offender's compliance with participation in a drug diversion program or with other conditions of probation or parole related to monitored drugs.
- (8) An epidemiologist with the Louisiana Department of Health for the purpose of assisting the board in analyzing prescription monitoring information in order to conduct public health evaluations to support public policy and education pursuant to an agreement with the board.
- F. The board may provide a report containing prescription monitoring information upon application of local, state, out-of-state, and federal law enforcement or prosecutorial officials, including judicially supervised specialty courts within the criminal justice system that are authorized by the Louisiana Supreme Court, engaged in the administration, investigation, or enforcement of the laws governing controlled substances or other drugs of concern in compliance with and as limited by the relevant requirements of any of the following:
  - (1) A court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer.
  - (2) A grand jury subpoena.
  - (3) An administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided by law enforcement to the board, and further, provided all of the following:
    - (a) The information sought is relevant and material to a legitimate law enforcement inquiry.
    - (b) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought.
    - (c) De-identified information, or limited information that does not identify or could not reasonably lead to the identification of an individual patient, could not reasonably be used.
- G. The board may provide prescription monitoring information in response to queries from prescription monitoring programs, electronic health information systems, and pharmacy information systems located in other states, territories, federal districts, and federal jurisdictions, through its participation in a secure interstate data exchange system. The prescription monitoring information made available pursuant in this Subsection may be used only in a manner consistent with this Section.
- H. The board may provide prescription monitoring information to authorized users of the prescription monitoring program via a state health information exchange or other third party conduit that has been approved by the board.
- I. The board may provide prescription monitoring information to any of the following persons in accordance with procedures established by board regulation:
  - (1) An individual who requests his personal prescription monitoring information.
  - (2) A parent, legal guardian, or legal healthcare agent, for the purpose of reviewing the history of monitored drugs dispensed to a child or an individual for whom the agent makes healthcare decisions, to the extent consistent with federal and state confidentiality laws and regulations.
  - (3) An executor of a will, or a court-appointed succession representative of an estate, for the purpose of reviewing the history of monitored drugs dispensed to a deceased individual.
- J. The board may disclose audit trail information to individuals identified in Paragraphs (E)(2) and Subsections F and I of this Section for use in an active investigation of an individual who submitted requests for prescription monitoring information.
- K. (1) The board and advisory council shall not be subject to civil liability, administrative action, or other legal or equitable relief for any of the following:
  - (a) Failure to possess prescription monitoring information that was not reported to the board.
  - (b) Release of prescription monitoring information or audit trail information that was factually incorrect.
  - (c) Release of prescription monitoring information or audit trail information to the wrong person or entity.
  - (d) Unlawful access to prescription monitoring information by an individual, or unlawful disclosure or use of prescription monitoring information by an individual who requested and received prescription monitoring information pursuant to this Section.

- (2) A dispenser or reporting agent shall not be subject to civil liability, administrative action, or other legal or equitable relief for reporting prescription monitoring information to the board.
- (3) A prescriber, dispenser, or other individual, agency, or entity in proper possession of prescription monitoring information or audit trail information pursuant to this Part shall not be subject to civil liability, administrative action, or other legal or equitable relief for accessing, using, or disclosing prescription monitoring information or audit trail information pursuant to the provisions of this Section.

(Section amended by Act 488 of the 2010 Regular Session; Act 352 of the 2012 Regular Session; Act 110 of the 2013 Regular Session; Act 22 of the 2015 Regular Session; Act 241 of the 2017 Regular Session; Acts 206 and 232 of the 2018 Regular Session; Act 80 of the 2019 Regular Session)

### §1008. Education and treatment

- A. The board shall, in consultation with and upon the recommendation of the advisory council, implement the following education courses:
  - (1) A course for persons who are authorized to access the prescription monitoring information, but who have violated the laws or breached occupational standards involving the prescribing, dispensing, or use of any controlled substances or drugs monitored by the prescription monitoring program.
  - (2) A continuing education course for healthcare providers or professionals on prescribing practices, pharmacology, and the identification, treatment, and referral of a patient addicted to or abusing controlled substances or drugs monitored by the prescription monitoring program.
- B. The board shall, in consultation with and upon recommendation of the advisory council, implement an educational program to inform the public about the use, diversion and abuse of, addiction to, and treatment for the addiction to controlled substances or drugs monitored by the prescription monitoring program.
- C. The board shall, upon reasonable suspicion, refer potential or alleged impaired prescribers and dispensers to the appropriate professional licensing or certification agency to ensure intervention, treatment, and ongoing monitoring and follow-up.

(Section amended by Act 241 of the 2017 Regular Session)

### §1009. Unlawful acts and penalties

- A. A dispenser who fails to submit prescription monitoring information to the board as required by this Part, or who fails to correct or amend data after notification by the board, shall be referred to the appropriate professional licensing, certification, or regulatory agency for administrative sanctions as deemed appropriate by that agency.
- B. A person or entity authorized to possess prescription monitoring information pursuant to this Part who knowingly accesses or discloses such information in violation of this Part shall be referred to the appropriate professional licensing, certification, or regulatory agency for administrative sanctions as deemed appropriate by that agency and may, upon criminal conviction, be imprisoned, with or without hard labor, for not more than five years, and in addition, may be fined not more than five thousand dollars.
- C. A person or entity authorized to possess prescription monitoring information pursuant to this Part who uses such information in a manner or for a purpose in violation of this Part shall be referred to the appropriate professional licensing, certification, or regulatory agency for administrative sanctions as deemed appropriate by that agency and may, upon criminal conviction, be imprisoned, with or without hard labor, for not more than five years, and in addition, may be fined not more than five thousand dollars.

(Section amended by Act 241 of the 2017 Regular Session)

### §1010. Evaluation; data analysis; reporting

- A. The board shall, in consultation with and upon recommendation of the advisory council, design and implement an evaluation component to identify cost benefits of the prescription monitoring program and other information relevant to policy, research, and education involving controlled substances and drugs monitored by the prescription monitoring program.
- B. The board shall report to the appropriate legislative oversight committees on a periodic basis, but in no case less than annually, the cost benefits and other information contained in Subsection A of this Section.

### §1011. Rules and regulations

In accordance with the Administrative Procedure Act, <u>R.S. 49:950</u> et seq., the board shall promulgate rules and regulations necessary to implement the provisions of this Part.

### §1012. Authority to contract

In accordance with the Public Bid Law, <u>R.S. 38:2211</u> *et seq.*, the board shall have the authority to contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. Any contractor shall be bound to comply with provisions regarding confidentiality of prescription information in <u>R.S. 40:1007</u>, and further, shall be subject to the penalties specified in <u>R.S. 40:1009</u> for unlawful acts.

### §1013. Funding authority

- A. The board shall have the authority to make application for, receive, and administer grant funding from public or private sources for the development, implementation, or enhancement of the prescription monitoring program.
- B. In the event the legislature provides full funding for the prescription monitoring program, no fees shall be levied as provided in this Section.
- C. The board shall have the authority to levy and collect an annual fee from each of the following practitioners in possession of authority to prescribe or dispense controlled dangerous substances: physicians, podiatrists, dentists, optometrists, advanced practice registered nurses, physician assistants, medical psychologists, or any other person subsequently authorized by law to prescribe controlled dangerous substances. The board shall also have the authority to levy and collect an annual fee from each pharmacy licensed by the board. The annual fee levied and collected from each person enumerated in this Subsection and each pharmacy shall not exceed twenty-five dollars.
- D. The board shall not be required to fund any aspect of the prescription monitoring program. (Section amended by Act 144 of the 2010 Regular Session; Act 27 of the 2013 Regular Session)

### §1014. Severability

If any provision of this Act or application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this Act which can be given effect without the invalid provisions or applications, and to this end the provisions of this Act are severable.

[End of Part X-A]

### Part X-C. Animal Euthanasia with Sodium Pentobarbital

[This new Part X-C, consisting of R.S. 40:1041 through 1046, also known as the Animal Euthanasia Act, was created by Act 225 of the 1987 Regular Session, effective August 1, 1987. Act 676 of the 2006 Regular Session re-numbered the Sections from 1031 through 1036. Subsequent amendments are noted herein.]

### §1031. Purpose

It is the purpose of this Part to establish a permit system to allow animal control facilities to acquire and administer sodium pentobarbital for the humane euthanasia of sick, homeless, and abandoned animals.

### §1032. Permit

No animal control agency or facility shall purchase, possess, or administer sodium pentobarbital to sick, homeless, injured, or unwanted pets or other domestic or wild animals for their humane euthanasia without the permit required by this Part.

### §1033. Permit application

Any duly incorporated humane society contracted to perform animal control services by a parish or municipality or any parish or municipal animal control agency may apply to the secretary of the Louisiana Department of Health for a permit to purchase, possess, and administer sodium pentobarbital for the humane euthanasia of animals.

### §1034. Permit issuance and conditions

- A. The secretary shall not issue a permit to purchase, possess, or administer sodium pentobarbital for the humane euthanasia of animals unless the following criteria have been met:
  - (1) The animal control agency or facility is a duly incorporated humane society contracted to perform animal control services by a parish or municipality or a parish or municipal animal control agency.
  - (2) The animal control agency has on staff a certified euthanasia technician, as provided in R.S. 37:1551 et seq.
  - (3) Any other criteria which may be established by the department pursuant to R.S. 40:1036.
- B. The permit shall designate a sole responsible person for the duration of the permit to oversee the purchase, possession, and administration of sodium pentobarbital, which such person shall be a certified euthanasia technician.

### §1035. Permit revocation or suspension; inspections

- A. The secretary may revoke or suspend any permit issued hereunder if it is determined that sodium pentobarbital is being used for any purpose other than humane animal euthanasia or that the permitted facility has failed to abide by the regulations promulgated by the secretary for the safe and efficient purchase, possession, or administration of sodium pentobarbital.
- B. The department shall inspect any permitted animal control facility to determine compliance with this Chapter or any rules or regulations promulgated pursuant thereto.

### §1036. Rules and regulations

The department may promulgate any rules and regulations necessary to effectuate the purposes of this Chapter.

[End of Part X-C]

### Part X-F. Ephedrine, Pseudoephedrine, and Phenylpropanolamine Monitoring Act

[This new Part X-F, consisting of Sections 1049.1 through 1049.11, was created by Act 314 of the 2009 Regular Session, effective August 15, 2009. Subsequent amendments are noted herein.]

### §1049.1. Short title

This Part may be referred to and may be cited as the "Ephedrine, Pseudoephedrine, and Phenylpropanolamine Monitoring Act".

### §1049.2. Legislative findings

- A. The Louisiana Legislature recognizes the devastating effect methamphetamine production has had on its citizens.
- B. Methamphetamine is unique in that it is a synthetic drug which can be produced by someone who does not possess specialized skill or training, is highly addictive, and can be made from inexpensive readily accessible ingredients.
- C. Methamphetamine has been reported as one of the most addictive and deadly drug threats in the United States. The use of methamphetamine can result in fatal kidney and lung disorders, brain damage, liver damage, chronic depression, psychosis, hallucinations, and many other devastating physical and mental effects.
- D. Louisiana has experienced a drop in methamphetamine production as restrictions on the sale of ephedrine, pseudoephedrine, and phenylpropanolamine have been implemented.
- E. Methamphetamine is not only deadly because of the devastating effects of drug addiction, but the production of methamphetamine has resulted in several laboratory explosions and the exposure of our citizens to death, injury, or toxic substances.
- F. While the production of methamphetamine has resulted in devastating effects on Louisiana citizens, the drugs used in making methamphetamine: ephedrine, pseudoephedrine, and phenylpropanolamine have legitimate medical uses.
- G. The Legislature of Louisiana hereby finds and declares that a pharmacist is in the unique position of dispensing nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine and interacting with the patient at the point of purchase of these products. This relationship with the consumer and the pharmacists' specialized knowledge about the pharmaceutical qualities of products containing ephedrine, pseudoephedrine, and phenylpropanolamine make the pharmacy the best location for the sale of those products to ensure the health and safety of Louisiana's citizens.
- H. The Louisiana Legislature, in enacting the provisions of this Part, seeks to provide for the legitimate medical needs of our citizens while at the same time protecting our citizens against the devastating effects of methamphetamines and methamphetamine production.
- I. In order to assist law enforcement and prosecutorial agencies in addressing the growing problems associated with methamphetamine production, a real time electronic database is needed to record purchases of products containing ephedrine, pseudoephedrine, and phenylpropanolamine at a pharmacy.
- J. Technology is available to record all purchases of products containing ephedrine, pseudoephedrine, and phenylpropanolamine at the point of sale and to transmit that information to a centralized location to be monitored and maintained in a central computer monitoring system operated by the Louisiana State Police.

# §1049.3. Restriction on the sale of nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine or their salts, optical isomers, and salts of optical isomers

- A. A nonprescription material, compound, mixture, or preparation containing any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers shall be dispensed, sold, or distributed only by a licensed pharmacist, certified pharmacy technician, or pharmacy employee permitted by the Louisiana Board of Pharmacy.
- B. A nonprescription material, compound, mixture, or preparation containing any detectable quantity of ephedrine, pseudoephedrine, or phenylpropanolamine, their salts or optical isomers, or salts of optical isomers shall not be dispensed, sold, or distributed by a pharmacist, certified pharmacy technician, or pharmacy employee to any person unless the following occur:
  - (1) The purchaser produces a federal or state issued photo identification, or a document that, with respect to identification, is considered acceptable for purposes of Sections <u>274a.2(b)(1)(v)(A)</u> and 274a.2(b)(1)(v)(B) of Title 8, Code of Federal Regulations (as in effect on or after March 9, 2006).
  - (2) The purchaser signs a written or electronic log or receipt showing the date of the transaction, the name of the purchaser, and the amount of the material, compound, mixture, or preparation sold.
  - (3) The transaction information is recorded by the pharmacy and transmitted to the central computer monitoring system as provided for in this Part.

- C. (1) A pharmacist, certified pharmacy technician, or pharmacy employee may sell or distribute nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine; however, those drugs shall not be distributed in a quantity greater than nine grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base, to the same purchaser within any thirty-day period.
  - (2) A pharmacist, certified pharmacy technician, or pharmacy employee selling or distributing nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine shall be exempt from the rules relative to the recordkeeping requirements for the dispensing of those nonprescription controlled dangerous substances; however, the pharmacist, certified pharmacy technician, or pharmacy employee shall record the transaction information and transmit it to the central computer monitoring system as provided for in this Part.
- D. (1) No person shall purchase, receive, or otherwise acquire more than nine grams of any product, mixture, or preparation described in Subsection A of this Section within any thirty-day period.
  - (2) The requirements of this Section shall not apply to any quantity of such product, mixture, or preparation dispensed pursuant to a valid prescription from a licensed practitioner with prescriptive authority.
- E. A law enforcement officer may, pursuant to <u>R.S. 40:986(B)</u>, obtain an administrative search warrant to inspect the written logs or receipts maintained at a pharmacy pursuant to the provisions of this Section.
- F. A parish or municipal government authority may regulate the selling, delivering, or providing of packages or grams of pseudoephedrine, ephedrine, or phenylpropanolamine only in a manner that is not more or less restrictive than regulation by the state under this Section.

# §1049.4. Central computer monitoring system; system requirements

- A. In order to facilitate the monitoring of sales of nonprescription products containing ephedrine, pseudoephedrine, or phenylpropanolamine the pharmacist, certified pharmacy technician, or other pharmacy employee shall record all of the following information at the point of sale regarding the transaction:
  - (1) The date of the transaction.
  - (2) The name and address of the purchaser verified through photo identification of the purchaser as provided for in R.S. 40:1049.3(B)(1).
  - (3) The name, quantity of packages, and total gram weight of the product or products purchased, received, or otherwise acquired.
- B. Upon recordation of the transaction information, the pharmacy shall transmit the information immediately to a central computer system for purposes of monitoring the sales of these products as provided for in this Section.
- C. The central computer system authorized by the provisions of this Section shall be designed and operated to allow the monitoring and reading of sales information regarding products containing ephedrine, pseudoephedrine, and phenylpropanolamine at the point of sale instantly and on a real-time basis.
- D. The central computer system authorized by the provisions of this Section shall be located within and administered by the Department of Public Safety and Corrections, office of state police.
- E. The central computer monitoring system shall provide for the monitoring of sales of compounds containing ephedrine, pseudoephedrine, and phenylpropanolamine and shall be capable of providing an online computer alert, to ensure direct scrutiny of conditions which would violate the provisions of this Part by law enforcement.
- F. The provisions of this Part shall not be construed to require that any pharmacy maintain the transaction records required under the provisions of this Part separate from the log book that is required under 21 U.S.C. 830(e). Use of the central computer monitoring system as required by this Part shall be deemed to satisfy both of these purposes.

#### §1049.5. Funding sources; no fees on pharmacists or pharmacies

- A. Funding for the acquisition, implementation, and operation of the central computer monitoring system shall be funded through appropriation, gifts, grants, donations, or any other funding sources not otherwise prohibited by law.
- B. Thereafter, the maintenance of the central computer monitoring system shall be funded through appropriation, gifts, grants, donations, or any other funding sources not otherwise prohibited by law.
- C. The Department of Public Safety and Corrections, office of state police, and the Louisiana Sheriffs' Association may actively seek gifts, grants, and donations that may be available through the federal government or other sources to help fund the central computer monitoring system, provided that such gifts, grants, and donations are not otherwise prohibited by law or rule.
- D. No fee shall be charged to any pharmacist or pharmacy to defray the costs of acquiring, implementing, or maintaining the central computer monitoring system as authorized by the provisions of this Part, nor shall any fee be charged to any pharmacist or pharmacy for the transmission of information to the central computer monitoring system.

#### §1049.6. Shared information; state police; sheriffs

- A. The Department of Public Safety and Corrections, office of state police, shall share the information regarding the sale of products containing ephedrine, pseudoephedrine, or phenylpropanolamine as authorized by the provisions of this Part and provide instant access to the Louisiana Sheriffs' Association.
- B. The Department of Public Safety and Corrections, office of state police, is authorized to enter into a cooperative endeavor, memorandum of understanding, contract, or any other agreement with the Louisiana Sheriffs' Association, or any other law enforcement agency in order to share the information regarding the sale of products containing ephedrine, pseudoephedrine, or phenylpropanolamine as authorized by the provisions of this Part and to provide instant access to all appropriate law enforcement agencies.

#### §1049.7. Board of pharmacy access to information

The Department of Public Safety and Corrections, office of state police, shall provide access to the information regarding the sale of products containing ephedrine, pseudoephedrine, or phenylpropanolamine as authorized by the provisions of this Part to the Louisiana Board of Pharmacy.

(Section amended by Act 206 of the 2018 Regular Session)

# §1049.8. Pharmacists, certified pharmacy technician, or pharmacy employee not required to stop sale; may report

- A. (1) The provisions of this Part shall not be construed to require a pharmacist, certified pharmacy technician, or pharmacy employee to prohibit or complete a sale of a product containing ephedrine, pseudoephedrine, or phenylpropanolamine even if the pharmacist, certified pharmacy technician, or other pharmacy employee observes a warning or signal from the central computer monitoring program which indicates that the purchaser has purchased those products in amounts which exceeds the amount which can be purchased by law.
  - (2) The provisions of this Part shall not be construed to limit a pharmacist's professional judgment as otherwise provided for by law or rules adopted by the Louisiana Board of Pharmacy.
- B. A pharmacist, certified pharmacy technician, or pharmacy employee may report suspected violations of this Section or any other law to any local, state, or federal law enforcement agency, or the appropriate prosecutorial agency for further investigation or prosecution.
- C. No pharmacist, certified pharmacy technician, or pharmacy employee who in good faith reports suspected violations as provided for in this Part shall be liable to any person or entity for any claim of damages as a result of the act of reporting the information, and no lawsuit may be predicated thereon.

# §1049.9. Licensed practitioner with prescriptive authority exempted

A health care practitioner with prescriptive authority who is licensed in the state of Louisiana shall be exempt from the requirements of the provisions of this Part in dispensing any product containing ephedrine, pseudoephedrine, or phenylpropanolamine to his patient.

# §1049.10. Transmission of information contingent on functionality of central computer monitoring system

- A. The transmittal of transaction information of products containing ephedrine, pseudoephedrine, and phenylpropanolamine as authorized by the provisions of this Part is contingent upon the acquisition, implementation, and operation of the central computer system.
- B. No licensed pharmacist, certified pharmacy technician, or pharmacy employee at a pharmacy located in Louisiana and permitted by the Louisiana Board of Pharmacy shall be required to transmit data to the central computer monitoring system until the funding for the acquisition and implementation of the central computer monitoring system has been secured through appropriation, gifts, grants, donations, or any other funding sources not otherwise prohibited by law.
- C. No pharmacy, licensed pharmacist, certified pharmacy technician, or pharmacy employee at a pharmacy located in Louisiana and permitted by the Louisiana Board of Pharmacy shall be held responsible for failure to transmit transaction information as required by this Part if at any time the central computer monitoring system is rendered inoperable due to natural disaster, tampering, or any other reason.

# §1049.11. Limitation of liability

A. The owner or operator of a retail pharmacy, who has submitted to the United States Attorney General a self-certification in accordance with the requirements of <u>21 U.S.C. 830(e)</u> regarding training of employees engaged in the sale of products containing ephedrine, pseudoephedrine, or phenylpropanolamine shall not be liable for

- violations of this Act by the retail pharmacy's employees.
- B. No licensed pharmacist, certified pharmacy technician, or pharmacy employee at a pharmacy located in Louisiana and permitted by the Louisiana Board of Pharmacy shall be personally liable for any act or omission resulting in damage, injury, or loss arising out of the dispensing of a compound containing ephedrine, pseudoephedrine, or phenylpropanolamine and the transmittal of that transaction to the central computer monitoring program as authorized by the provisions of this Part; however, this limitation of liability shall not be applicable if the damage, injury, or loss was caused by the gross negligence or willful or wanton misconduct of the pharmacist, certified pharmacy technician, or pharmacy employee.

[End of Part X-F]

#### Part XV. Dimethyl Sulfoxide (DMSO)

[This new Part XV, consisting of R.S. 40:1060, was created by Act 635 of the 1980 Regular Session, effective August 1, 1980. Subsequent amendments are noted herein.]

#### §1060. Use of dimethyl sulfoxide (DMSO)

- A. No hospital or health facility shall interfere with the physician/patient relationship by restricting or forbidding the use of dimethyl sulfoxide, hereinafter referred to as "DMSO", when prescribed or administered by licensed physicians and requested by a patient unless a formal finding has been made by the state board of health that the substance as prescribed or administered by the physician is harmful. Furthermore, no hospital or health facility shall remove the staff privileges of a physician solely because said physician prescribed or administered DMSO to a patient under the conditions set forth in this Part.
- B. No licensed physician in this state shall be subject to disciplinary action by the state board of medical examiners and osteopathic examiners for prescribing or administering DMSO to a patient under his care who has requested the substance unless the state boards have made a formal finding that the substance is harmful.
- C. The patient, upon request for the administration of DMSO and after being fully informed as to alternative methods of treatment, shall sign a written statement releasing the physician and, when applicable, the hospital or health facility from any liability from damages which may arise from the use of DMSO.

[End of Part XV]

#### Part XVI. Legend Drugs

[This new Part XVI, consisting of R.S. 40:1237 and 40:1238, was created by Act 872 of the 1982 Regular Session. Subsequent amendments are noted herein.]

#### **§1060.11. Definitions**

For the purpose of this Part:

- (1) "Code imprint" means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug, or marks or monograms unique to the manufacturer, distributor, or both. The National Drug Code may be used as a code imprint.
- (2) "Distributor" means any corporation, person, or entity not engaged in the manufacturer of a legend drug product, who distributes for resale and distribution a legend drug product under the label of such corporation, person, or entity.
- (3) "Legend drug" means any drug or drug product bearing on the label of the manufacturer or distributor, as required by the Federal Food and Drug Administration, the statement "Caution: Federal law prohibits dispensing without prescription."
- (4) "Solid dosage forms" means capsules or tablets intended for oral administration. (HCR 84 of the 2015 Regular Session re-designated the original Section 1237 as R.S. 40:1060.11)

#### §1060.12. Legend drug imprint

- A. No legend drug in solid dosage form may be manufactured or distributed for sale in this state unless there is clearly marked or imprinted on the dosage form a code imprint identifying the drug and the manufacturer or distributor of the drug. The Louisiana Department of Health, upon application by a manufacturer or distributor, may exempt a particular drug product from the requirement to be imprinted on the grounds that imprinting is not feasible because of said drug product's size, texture, or other unique characteristics.
- B. On or before January 1, 2984, manufacturers or distributors of legend drugs shall provide to the Louisiana Department of Health a list of their legend drugs and the description of the code imprint each bears. The department shall provide for the distribution of the information required to be submitted under this Part to all poison control centers in the state. The department shall provide to any licensed healthcare provider, upon request, lists of legend drugs and code imprints provided to the department under this Section, but may charge a reasonable fee to cover copying and postage costs. Manufacturers and distributors shall provide updated lists to the department annually or as changes or revisions occur.
- C. A legend drug that does meet the above requirements shall be deemed misbranded.
- D. Whoever manufactures or distributes for sale or otherwise provides to any other person for dispensing any legend drug in solid dosage form that fails to comply with this Section shall be fined twenty-five thousand dollars, or imprisoned for five years, or both.
- E. The provisions of Subsections A, B. C, and D of this Section shall not apply to any of the following:
  - (1) Drugs purchased by a pharmacy, pharmacist, or licensed wholesaler prior to January 1, 1984, and held in stock for resale.
  - (2) Drugs which are manufactured by or upon the order of a practitioner licensed by law to prescribe or administer drugs and which are to be used solely by the patient for whom prescribed.

(HCR 84 of the 2015 Regular Session re-designated the original Section 1238 as R.S. 40:1060.12)

# §1060.13. Sale, distribution, or possession of legend drug without prescription or order prohibited; exceptions; penalties

- A. It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician or licensed healthcare practitioner as defined in R.S. 40:961(35). This Section shall not apply to sale, delivery, or possession by drug wholesalers or drug manufacturers, or their agents or employees, or to any practitioner acting within the scope of his license, or to a common or contract carrier or warehouseman, or any employee thereof, whose possession of any legend drug is in the usual course of business or employment.
- B. Any person who violates the provisions of this Section shall be fined not more than five hundred dollars, imprisoned for not more than six months, or both.

(Section added as R.S. 40:1238.1 by Act 565 of the 2006 Regular Session; amended by Act 287 of the 2007 Regular Session; Act 360 of the 2010 Regular Session; re-designated as R.S. 40:1060.13 by HCR 84 of the 2015 Regular Session; amended by Act 203 of the 2018 Regular Session)

#### §1060.14. Prescription requirements; penalties

A. A prescription, in order to be effective in legalizing the possession of legend drugs, shall be issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs. An order purporting to be a

prescription issued to a drug abuser or habitual user of legend drugs, not in the course of professional treatment, is not a prescription within the meaning and intent of this Section. Any person who knows or should know that he or she is filling such a prescription or order to a drug abuser or habitual user of legend drugs, as well as the person issuing the prescription, may be charged with a violation of this Section. A legitimate medical purpose shall include use of the drug in the course of a bona fide research program in conjunction with a hospital or university.

B. Any person who violates the provisions of this Section shall be imprisoned, with or without hard labor, for not more than five years and may be sentenced to pay a fine of not more than five thousand dollars.

(Section added as R.S. 40:1238.2 by Act 565 of the 2006 Regular Session; re-designated as R.S. 40:1060.14 by HCR 84 of the 2015 Regular Session)

#### §1060.15. Obtaining legend drugs by misrepresentation or fraud; penalties

- A. It shall be unlawful for any person knowingly or intentionally to acquire or obtain possession of a legend drug by misrepresentation, fraud, forgery, deception or subterfuge.
- B. Any person who violates the provisions of this Section shall be fined not more than five hundred dollars, imprisoned for not more than six months, or both.

(Section added as R.S. 40:1238.3 by Act 565 of the 2006 Regular Session; re-designated as R.S. 40:1060.15 by HCR 84 of the 2015 Regular Session; amended by Act 203 of the 2018 Regular Session)

#### §1060.16. Prescriptions; electronic questionnaires

- A. As used in this Section, the following terms shall have the following meanings unless the context clearly indicates otherwise:
  - (1) "Electronic questionnaire" means a computer-assisted system for collecting a person's healthcare data.
  - (2) "Valid physician-patient relationship" means a medical relationship that exists when the practitioner has conducted at least one medical evaluation with a person in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other practitioners.
- B. A prescription issued solely upon the results of answers to an electronic questionnaire, in the absence of a documented patient evaluation including a physical examination, shall be considered issued outside the context of a valid physician-patient relationship and shall not be a valid prescription.
- C. If a pharmacist knowingly dispenses a prescription authorized solely on the result of an electronic questionnaire, he shall be in violation of this Section.
- D. A pharmacist who knows that a prescription has been authorized in the absence of a valid physician-patient relationship, or otherwise in violation of the prescriber's standard of practice, shall not fill such prescription.
- E. A pharmacist who dispenses prescription drugs in violation of this Section is not acting in the best interest of the patient and is dispensing outside the course of the professional practice of pharmacy.
- F. A pharmacist who violates the provisions of this Section shall be imprisoned, with or without hard labor, for not more than five years and may be sentenced to pay a fine of not more than five thousand dollars.

(Section added as R.S. 40:1238.4 by Act 318 of the 2007 Regular Session; re-designated as R.S. 40:1060.16 by HCR 84 of the 2015 Regular Session)

[End of Part XVI]

#### Part XVII. Anabolic Steroid

[This new Part XVII, consisting of R.S. 40:1239, was created by Act 362 of the 1988 Regular Session. Subsequent amendments are noted herein.]

#### §1060.21. Uses authorized; regulation; penalties

- A. The provisions of this Section and of the <u>Uniform Controlled Dangerous Substances Law</u> do not apply to anabolic steroids that are expressly intended for administration to livestock or other nonhuman species, that are approved by the federal Food and Drug Administration for such use.
- B. "Anabolic steroid" as used herein means any anabolic steroid or synthetic derivative of testosterone, including but not limited to the following:
  - (1) Bodenone.
  - (2) Chlorotestosterone.
  - (3) Clostebol.
  - (4) Chorionic gonadotropin.
  - (5) Dehydrochlormethyltestosterone.
  - (6) Dihydrotestosterone.
  - (7) Drostanolone.
  - (8) Ethylestrenol.
  - (9) Fluoxymesterone.
  - (10) Mesterolone.
  - (11) Methandienone.
  - (12) Methandranone.
  - (13) Methandriol.
  - (14) Methandrostenolone.
  - (15) Methyltestosterone.
  - (16) Mibolerone.
  - (17) Nandrolone.
  - (18) Norethandrolone.
  - (19) Oxandrolone.
  - (20) Oxymesterone.
  - (21) Oxymetholone.
  - (22) Stanolone.
  - (23) Stanozolol.
  - (24) Testolactone.
  - (25) Testosterone.
  - (26) Trenbolone.
- C. (1) A physician, dentist, or veterinarian shall not prescribe, dispense, deliver, or administer an anabolic steroid for human use or cause an anabolic steroid to be administered under his direction or supervision for human use except for a valid medical purpose and when required by demonstrable generally accepted medical indications. Bodybuilding, muscle enhancement, or increasing muscle bulk or strength through the use of an anabolic steroid by a person who is in good health is not a valid medical purpose.
  - (2) Whoever violates the provisions of this Subsection shall be subject to suspension or revocation of his license to practice medicine, dentistry, or veterinary medicine by his governing board.
  - (3) Whoever violates the provisions of this Subsection shall also be fined not more than five thousand dollars or imprisoned with or without hard labor for not more than five years, or both.

(Section amended by Acts 345 and 704 of the 1989 Regular Session; Act 542 of the 1990 Regular Session; Act 2 of the 1991 First Extraordinary Session; re-designated as R.S. 40:1060.21 by HCR 84 of the 2015 Regular Session)

[End of Part XVII]

[End of Chapter 4]

#### **Chapter 5 – Health Provisions: Abortion**

#### §1061. Abortion; prohibition

- A. The provisions of this Act shall become effective immediately upon, and to the extent permitted by, the occurrence of any of the following circumstances:
  - (1) Any decision of the Supreme Court of the United States which overrules, in whole or in part, Roe v. Wade, 410 U.S. 113, 93 S.Ct. 705, 35 L.Ed. 2d 147 (1973), thereby restoring to the state of Louisiana the authority to prohibit or limit abortion.
  - (2) Adoption of an amendment to the United States Constitution which, in whole or in part, restores to the state of Louisiana the authority to prohibit or limit abortion.
  - (3) A decision of the Supreme Court of the United States in the case of <u>Dobbs v. Jackson Women's Health</u>
    <u>Organization, Docket No. 19-1392</u>, which overrules, in whole or in part, Roe v. Wade, 410 U.S. 113, 93
    S.Ct. 705, 35 L.Ed. 2d 147 (1973), thereby restoring to the state of Louisiana the authority to prohibit or limit abortion.
- B. The provisions of this Act shall be effective relative to the appropriation of Medicaid funds, to the extent consistent with any executive order by the President of the United States, federal statute, appropriation rider, or federal regulation that sets forth the limited circumstances in which states must fund abortion to remain eligible to receive federal Medicaid funds pursuant to 42 U.S.C. 1396 et seq.
- C. No person may knowingly administer to, prescribe for, or procure for, or sell to any pregnant woman any medicine, drug, or other substance with the specific intent of causing or abetting the termination of the life of an unborn human being. No person may knowingly use or employ any instrument or procedure upon a pregnant woman with the specific intent of causing or abetting the termination of life of an unborn human being.
- D. Any person in violation of this Section shall be prosecuted pursuant to the effective provisions of <u>R.S. 14:87.7</u>, and shall be subject to the penalties provided in R.S. 40:1061.29.
- E. Nothing in this Section may be construed to prohibit the sale, use, prescription, or administration of a contraceptive measure, drug or chemical, if it is administered prior to the time when a pregnancy could be determined through conventional medical testing and if the contraceptive measure is sold, used, prescribed, or administered in accordance with manufacturer instructions.
- F. It shall not be a violation of Subsection C of this Section for a licensed physician to perform a medical procedure necessary in reasonable medical judgment to prevent the death or substantial risk of death due to a physical condition, or to prevent the serious, permanent impairment of a life-sustaining organ of a pregnant woman. However, the physician shall make reasonable medical efforts under the circumstances to preserve both the life of the mother and the life of her unborn child in a manner consistent with reasonable medical practice.
- G. Medical treatment provided to the mother by a licensed physician which results in the accidental or unintentional injury or death to the unborn child is not a violation of Subsection C of this Section.
- H. Nothing in this Section may be construed to subject the pregnant mother upon whom any abortion is performed or attempted to any criminal conviction and penalty.
- I. The terms as used in this Section have the same meaning as the definitions provided in R.S. 14:87.1.
- J. This Section shall be known, and may be cited, as the Human Life Protection Act.

(Section originally added as R.S. 40.1299.30 by Act 467 of the 2006 Regular Session then re-designated to R.S. 40:1061 by HCR 84 of the 2015 Regular Session; amended by Act 468 of the 2018 Regular Session; Acts 545 and 548 of the 2022 Regular Session)

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#### §1061.11. Drugs or chemicals used; penalties

- A. When any drug or chemical is used for the purpose of inducing an abortion, the physician who prescribed the drug or chemical shall be in the same room and in the physical presence of the pregnant woman when the drug or chemical is initially administered, dispensed, or otherwise provided to the pregnant woman.
- B. The drug or chemical shall not be administered, dispensed, or otherwise provided to the pregnant woman by a physician or any person acting under the physician's direction, whether in a licensed outpatient abortion facility, private medical office or any other facility, unless the physician has obtained the voluntary and informed consent of the pregnant woman pursuant to the provisions of <u>R.S. 40:1061.17</u> and the requirements set forth in that Section
- C. If a physician prescribes, dispenses, administers, or provides any drug or chemical to a pregnant woman for the purpose of inducing an abortion, the physician shall report the abortion to the Louisiana Department of Health as

- provided in R.S. 40:1061.21.
- D. In addition to the requirements of reporting complications to the Louisiana Department of Health pursuant to R.S. 40:1061.21, if the physician knows that the woman experienced a serious adverse event, as defined by the MedWatch Reporting System, during or after the administration or use of the drug, the physician shall also report the event to the United States Food and Drug Administration through the MedWatch Reporting System not later than the third day after the date the physician learns that the event occurred.
- E. The Louisiana State Board of Medical Examiners may take disciplinary action as authorized in <u>R.S. 37:1261</u> *et seq.* or any other applicable provision of law against a physician who violates any provision of this Section.
- F. Any person not under the direct and immediate supervision of a physician who knowingly performs or attempts to perform an abortion using chemicals or drugs in violation of this Section shall be subject to penalties pursuant to R.S. 40:1061.29. No penalty may be assessed against the woman who undergoes the abortion.
- G. The provisions of <u>R.S. 40:1061.1</u> shall apply to this Section.

(Section originally added as R.S. 40:1299.35.2.1 by Act 259 of the 2013 Regular Session; amended by Act 620 of the 2014 Regular Session; section re-designated to R.S. 40:1061.11 by HCR 84 of the 2015 Regular Session; amended by Act 545 of the 2022 Regular Session)

\* \* \*

# §1061.11.1. Chemically induced abortion; required disclosure

- A. When mifepristone is administered, dispensed, or otherwise provided to a pregnant woman by a physician or any person acting under the physician's direction, whether in a licensed outpatient abortion facility, private medical office, or any other facility, then the physician or the person acting under the physician's direction shall provide the disclosure statement found in Subsection B of this Section to the pregnant woman. The disclosure statement may be provided by doing any of the following:
  - (1) Stapling the disclosure statement to a bag, envelope, or other package that contains misoprostol for the pregnant woman to self-administer at home.
  - (2) Attaching the disclosure statement to a written prescription for misoprostol provided by the physician or the person acting under the physician's direction.
  - (3) Attaching the disclosure statement to the patient's discharge instructions if the prescription for misoprostol is sent directly to a pharmacy.
- B. The disclosure statement required by this Section shall contain all of the following text:

"PLEASE READ BEFORE TAKING SECOND PILL

Research has indicated that the first pill provided, identified as mifepristone, is not always effective in ending a pregnancy. If after taking the first pill you regret your decision, please consult a physician or healthcare provider immediately to determine if there are options available to assist you in continuing your pregnancy."

- C. (1) Nothing in this Section shall be construed as creating or recognizing a right to abortion.
  - (2) Nothing in this Section shall be construed as requiring the disclosure statement to be provided to a woman facing a spontaneous miscarriage as defined in R.S. 14:87.1(1)(b)(ii).
  - (3) Nothing in this Section shall be construed as requiring a pharmacy or any entity other than the facility where the abortion is administered to provide the disclosure statement.
- D. As used in this Section, the following terms have the meanings ascribed to them:
  - (1) "Abortion pill" means the use of mifepristone or misoprostol to induce a chemical abortion.
  - (2) "Mifepristone" means a synthetic steroid that inhibits the action of progesterone, given orally in early pregnancy to induce a chemical abortion. Mifepristone is the first drug used in a two-drug process to induce a chemical abortion.
  - (3) "Misoprostol" means a synthetic prostaglandin E<sub>1</sub> analogue that is used to induce a chemical abortion. Misoprostol is the second drug used in a two-drug process to induce a chemical abortion.
- E. The provisions of <u>R.S. 40:1061.1</u> shall apply to this Section.

(Section added by Act 483 of the 2021 Regular Session; amended by Act 545 of the 2022 Regular Session)

\* \* \*

# §1061.20. Conscience in health care protection; definitions

A. (1) Any person has the right not to participate in, and no person shall be required to participate in any health care service that violates his conscience to the extent that patient access to health care is not compromised. No person shall be held civilly or criminally liable, discriminated against, dismissed, demoted, or in any way prejudiced or damaged for declining to participate in any health care service that violates his conscience.

- (2) This Section shall not prevent an inquiry by an employer or patient regarding whether a person declines to participate in any health care service that violates his conscience. When a patient requests health care services, a person shall identify, in writing, as soon as practicable, his declination to provide a service in accordance with the provisions of this Section. All persons who have a sincerely held religious belief or moral conviction and who seek employment at a health care facility shall notify the prospective employer of the existence of any sincerely held religious belief or moral conviction. Any health care facility that employs a person with a sincerely held religious belief or moral conviction shall ensure that the health care facility has sufficient staff to provide patient care in the event an employee declines to participate in any health care service that violates his conscience.
- (3) The provisions of this Section shall not be construed to relieve any health care provider from providing emergency care as required by state or federal law.
- (4) A person shall notify his employer in writing as soon as practicable of any health care service that violates his conscience. A person shall notify any patient before such person provides any consultation or service to the patient of the existence of a health care service that he will decline to provide because the health care service violates his conscience.
- B. For purposes of this Section:
  - (1) "Conscience" means sincerely held religious belief or moral conviction.
  - (2) "Health care service" is limited to abortion, dispensation of abortifacient drugs, human embryonic stem cell research, human embryo cloning, euthanasia, or physician-assisted suicide.
- C. A suit alleging a violation of this Section shall be brought in a district court in accordance with R.S. 23:303.
- D. The provisions of <u>R.S. 40:1061.1</u> shall apply to this Section.

(Section originally added as R.S. 40:1299.35.9 by Act 372 of the 2009 Regular Session; section re-designated as R.S. 40:1061.20 by HCR 84 of the 2015 Regular Session; amended by Act 545 of the 2022 Regular Session)

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[End of Chapter 5.0]

# **Chapter 5-A – Health Provisions: Children**

#### Part IX. The Stop Harming Our Kids Act

[This new Part IX, consisting of Sections 1098.1 through 1098.6 was created by Act 466 of the 2023 Legislature, effective January 1, 2024. Subsequent amendments are noted herein.]

#### §1098.1. Definitions

For the purposes of this Part, the following terms have the meaning ascribed to them unless the context clearly indicates otherwise:

- (1) "Healthcare professional" shall have the same meaning as the term is defined in R.S. 14:34.8.
- (2) "Minor" means any natural person who has not reached the age of majority as provided in <u>Civil Code Article 29</u> and who has not been emancipated pursuant to <u>Title V of Book VII of the Code of Civil Procedure.</u>
- (3) "Sex" means the biological indication of male or female as evidenced by a medical examination of all of the following:
  - (a) Sex chromosomes.
  - (b) Naturally occurring sex hormones.
  - (c) Gonads.
  - (d) As well as nonambiguous internal and external genitalia present at birth.

#### §1098.2. Healthcare professionals; restrictions

- A. A healthcare professional shall not knowingly engage in any of the following acts that attempt to alter a minor's appearance in an attempt to validate a minor's perception of the minor's sex, if the minor's perception is inconsistent with the minor's sex:
  - (1) The prescription or administration of gonadotropin-releasing hormone analogues or other synthetic drugs used to stop luteinizing hormone and follicle stimulating hormone secretion, synthetic antiandrogen drugs used to block the androgen receptor, or any drug to suppress or delay normal puberty.
  - (2) The prescription or administration of testosterone, estrogen, or progesterone, in amounts greater than would normally be produced endogenously in a healthy individual of the same age and sex.
  - (3) The performance of any sterilizing surgery, including but not limited to castration, hysterectomy, oophorectomy, orchiectomy, penectomy, and vasectomy.
  - (4) The performance of any surgery that artificially constructs tissue having the appearance of genitalia differing from the minor's sex, including metoidioplasty, phalloplasty, and vaginoplasty.
  - (5) The removal of any healthy or non-diseased body part or tissue.
  - (6) The performance of augmentation mammoplasty, facial feminization surgery, liposuction, lipofilling, pectoral implants, voice surgery, thyroid cartilage reduction, gluteal augmentation, hair reconstruction, or any aesthetic surgical procedure.
- B. The prohibited acts listed in Subsection A of this Section shall not be considered healthcare services.
- C. The prohibitions listed in Subsection A of this Section shall not limit or restrict the provision of healthcare:
  - (1) A minor born with a medically verifiable disorder of sex development, including but not limited to external sex characteristics that are irresolvably ambiguous.
  - (2) A minor diagnosed with a disorder of sexual development, if a healthcare professional has determined, through genetic or biochemical testing, that the minor does not have a sex chromosome structure, sex steroid hormone production, or sex steroid hormone action, that is normal for a biological male or biological female.
  - (3) A minor needing treatment for an infection, injury, disease, or disorder that has been caused or exacerbated by any action or procedure prohibited by this Part.
  - (4) A minor suffering from a physical disorder, physical injury, or physical illness that is certified by a healthcare provider and that would place the individual in imminent danger of death or impairment of major bodily function unless surgery is performed.
- D. If, prior to January 1, 2024, a healthcare professional has initiated a course of treatment, for a minor, which includes the prescription or administration of any drug or hormone prohibited by this Part, and if the healthcare professional determines and documents in the minor's medical record that immediately terminating the minor's use of the drug or hormone would cause harm to the minor, the healthcare professional may institute a period during which the minor's use of the drug or hormone is systematically reduced and discontinued. The period may not extend beyond December 31, 2024.

#### §1098.3. Healthcare professionals; disciplinary actions

If a professional or occupational licensing board finds, by a preponderance of the evidence, that a healthcare professional licensed or certified by the board has violated the provisions of this Part, the board shall revoke any professional or occupational license or certificate held by the healthcare professional for a minimum of two years.

#### §1098.4. Minors' lack of consent

- A. Notwithstanding the provisions of <u>R.S. 40:1079.1</u> and notwithstanding any other provision of law to the contrary, a minor may not consent to any procedures or services that are prohibited in <u>R.S. 40:1098.2</u>(A).
- B. The provisions of this Section shall not apply to a minor who is subject to the provisions of R.S. 40:1098.2(D).

# §1098.5. Civil actions; remedies

- A. Notwithstanding any other provision of law to the contrary, a person who has been harmed as a result of acts which are prohibited by this Part or who has been subjected to acts which are prohibited by this Part with or without consent, shall have a cause of action for damages in a court of competent jurisdiction.
- B. The cause of action for damages shall be commenced before the later of either of the following:
  - (1) The lapse of a twelve-year liberative prescription once the minor reaches the age of majority.
  - (2) Within three years from the time the person discovered or reasonably should have discovered that the injury or damages were caused by the violation.
- C. Venue pursuant to this Section may be brought pursuant to <u>Code of Civil Procedure Article 42</u> or in the parish of domicile of the petitioner.
- D. (1) If a court finds that a person is entitled to judgment pursuant to this Section, the court shall award damages, attorney fees, and all costs of the proceeding against the defendant for violation of this Part.
  - (2) Damages awarded by the court pursuant to this Section may include but is not to be limited to damages for infertility or sterility that is suffered by the minor as a result of the acts prohibited by this Part.
- E. Consent shall not operate as a defense to a petitioner's claim that is filed pursuant to this Section.

#### §1098.6. Attorney general; injunctive or declaratory relief

- A. The attorney general may bring a civil action to enforce compliance with this Part in a court of competent jurisdiction.
- B. The attorney general may seek injunctive relief or declaratory relief and any other appropriate remedy from in order to protect a minor from those harms resulting from conduct that is prohibited pursuant to this Part.
- C. Venue pursuant to this Section shall be that same venue which is provided in R.S. 40:1098.5.
- D. If the court grants relief pursuant to this Section, the court shall award attorney fees and all costs of the proceeding against the defendant for violation of this Part.
- E. Nothing in this Part shall be construed to deny, impair, or otherwise affect any right or authority of the attorney general, the state, or any agency, officer, or employee of the state to institute or intervene in any proceeding.

[End of Part IX]

[End of Chapter 5-A]

# **Chapter 5-B – Health Provisions: Diseases and Conditions**

#### Part X. Venereal Diseases

#### **Subpart A. General Provisions**

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#### §1121.6. Expedited partner therapy

- A. The purpose of this Section is to allow for the provision of medications or prescriptions by any physician licensed to practice medicine in this state or any advanced practice registered nurse who is licensed to practice nursing in this state, or any physician assistant who is licensed to practice in this state, provided such physician or nurse or physician assistant has the authority to write prescriptions in this state, to individuals who may have been exposed to gonorrhea or chlamydia. Expedited partner therapy is hereby authorized absent a doctor-patient relationship and absent clinical assessment.
- B. Notwithstanding any other provisions of law to the contrary, any physician or any advanced practice registered nurse who diagnoses or does a nurse clinical assessment or any physician assistant who performs an examination of a case of chlamydia or gonorrhea in an individual patient may prescribe, furnish, or otherwise provide prescription antibiotic drugs to that patient's sexual partner or partners absent a doctor-patient relationship or absent an advanced practice registered nurse-patient relationship and without examination or nurse clinical assessment or physician assistant examination of that patient's sexual partner or partners.
- C. If expedited partner therapy is chosen as an alternative, the patient with a case of chlamydia or gonorrhea will be given a written document that he agrees to give to his sexual contact. The document will contain, but will not be limited to, the following information:
  - (1) The sexual contact should be examined and treated by a physician, advanced practice registered nurse or physician assistant, if at all possible.
  - (2) The medicine or prescription for medicine given to the sexual contact by the patient should not be taken by the contact if the contact has a history of allergy to the antibiotic or to the pharmaceutical class of antibiotic in which case the sexual contact should be examined and treated by a physician, advanced practice registered nurse or physician assistant and offered another type of antibiotic treatment.
  - (3) The medicine or prescription for medicine given to the sexual contact by the patient should not be taken by the contact if the contact is pregnant, in which case the sexual contact should be examined by the prenatal health care provider.
- D. Any pharmacist licensed to practice pharmacy in this state may recognize a prescription authorized by this Section as valid notwithstanding any other provision of law or administrative rule to the contrary.
- E. The provisions of this Section which relate to expedited partner therapy shall be implemented according to rules promulgated by the secretary of the Department of Health in accordance with the <u>Administrative Procedure Act</u>. (Section added by Act 449 of the 2008 Regular Session; re-designated to R.S. 40:1121.6 by HCR 84 of the 2015 Regular Session)

[End of Subpart X-A]

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[End of Chapter 5-B]

# **Chapter 5-C – Health Provisions: Emergency Medical Services**

#### **Part VII. Emergency Medications**

[This new Part VII, consisting of Section 1142, was created by Act 657 of the 2024 Regular Session, effective August 1, 2024. Subsequent amendments are noted herein.]

#### §1142. Allowance to stock emergency medications; definitions

- A. For the purposes of this Section, the following definitions apply:
  - (1) (a) "Life-saving medications" means any medication recognized by the Louisiana Department of Health as a medication that can be administered to treat a life-threatening condition.
    - (b) Such medications may include but shall not be limited to the following:
      - (i) Epinephrine.
      - (ii) Naloxone.
      - (iii) Albuterol.
      - (iv) Glucagon
  - (2) "Qualified entity" means any public or private entity that is associated with a location where a medical emergency can occur, including licensed early learning centers, colleges and universities, places of employment, restaurants, amusement parks, recreation camps, after-school programs, sports playing fields and arenas, and other similar locations, except that "qualified entity" does not include public or non-public elementary or secondary schools.
  - (3) "Trained personnel" means an employee, agent, or volunteer of an entity who has received training on the medications that include but are not limited to the following:
    - (a) Techniques on how to recognize signs of life-threatening emergency standards and procedures for the storage and administration of life-saving medication.
    - (b) Emergency follow-up procedures including the requirement to summon emergency services either immediately before or immediately after administering life-saving medication.
- B. Notwithstanding any other provision of law to the contrary, licensed healthcare professionals authorized to prescribe such medication may prescribe life-saving medications maintained in the name of a qualified entity for use in accordance with this Section.
- C. Notwithstanding any other provision of law to the contrary, licensed pharmacists and physicians may dispense life-saving medications in accordance with a prescription issued pursuant to this Section.
- D. Notwithstanding any other provision of law to the contrary, a qualified entity may maintain a stock supply of life-saving medication in accordance with a prescription issued pursuant to this Section.
- E. (1) The qualified entity may authorize trained personnel to administer life-saving medications to an individual on the qualified entity's premises or during a qualified entity-affiliated activity with whom the trained personnel as defined in this Section believes in good faith is experiencing a medical emergency, in accordance with this Section. There shall be a standing protocol for a licensed healthcare professional authorized to dispense or prescribe the necessary medication, regardless of whether the individual has a prescription for a life-saving medication.
  - (2) Training may be performed by a medical emergency training organization, a registered nurse, or a licensed physician.
- F. The qualified entity may enter into arrangements with manufacturers of life-saving medication or third-party suppliers of life-saving medications to obtain life-saving medications at fair-market, free, or reduced prices.
- G. A person or entity shall not be liable for damages in a civil action for injury, death, or loss to person or property that allegedly arises from an act or omission associated with administration or self-administration of a life-saving mediation, unless the act or omission constitutes willful or wanton misconduct. The limitation of liability provided for in this Subsection shall apply to the following:
  - (1) A qualified entity.
  - (2) A qualified entity's employee, agent, or volunteer.
  - (3) A licensed healthcare professional authorized to prescribe or dispense life-saving medications.
  - (4) A training organization and its personnel.
- H. The administration of life-saving medications pursuant to this Section is not the practice of medicine or nursing.
- I. (1) Notwithstanding any other provision of law to the contrary, the secretary of the Louisiana Department of Health is authorized to issue a standing order for the prescription of life-saving medications on a statewide basis under certain conditions that he shall determine to be in the best interest of the people in this state.

- (2) If the secretary of the department is not a physician, the secretary may appoint a designee who is a physician employed by the department to issue the standing order provided for in this Subsection.
- J. The Louisiana Department of Health shall promulgate rules in accordance with the <u>Administrative Procedure Act</u> to implement the provisions of this Section. The rules shall include the list of life-saving medications that can be prescribed, dispensed, and maintained pursuant to the provisions of this Section.

[End of Part VII]

[End of Chapter 5-C]

#### **Chapter 5-D – Health Provisions: Health Care**

#### **Subchapter A – Healthcare Consumers**

# Part I. Advance Directives and Life-Sustaining Procedures

# **Subpart D. Prescription Nonopioid Directive**

#### §1156.1. Voluntary nonopioid directive; form; immunity

- A. The Louisiana Department of Health, in consultation with the office of behavioral health, shall establish a voluntary nonopioid directive form and shall publish the form prominently on the department's website for public use.
- B. A patient may execute and file a voluntary nonopioid directive form with a prescribing practitioner when the patient does not wish to be issued a prescription or medication order for an opioid. Upon receipt of a voluntary nonopioid directive form, a prescribing practitioner shall date and affix his signature to the form in the presence of the patient as evidence of acceptance, document the receipt in the patient's medical record, and provide a signed copy of the form to the patient.
- C. The voluntary nonopioid directive form established by the department shall allow a patient or when the patient is unable to consent for himself, any person duly authorized and empowered to provide medical consent for the patient under the provisions of <u>R.S. 40:1151.4</u>, to revoke the directive, orally or in writing, for any reason, at any time.
- D. An electronically transmitted prescription to a pharmacy shall be presumed to be valid for the purposes of this Section, and a pharmacist shall not be held in violation of this Section for dispensing a controlled substance in contradiction to a voluntary nonopioid form.
- E. No prescribing practitioner who has signed and executed a nonopioid directive form with a patient acting with reasonable care shall be liable for damages in a civil action or subject to criminal prosecution or be deemed to have violated the standard of care for such prescribing practitioner for refusing to issue a prescription or medication order for an opioid pursuant to a voluntary nonopioid directive form.
- F. No person acting in good faith as a duly authorized guardian or healthcare representative pursuant to Subsection C of this Section shall be liable for damages in a civil action or subject to criminal prosecution for revoking or overriding a voluntary nonopioid directive form.
- G. No prescribing practitioner shall be liable for damages in a civil action, subject to criminal prosecution, or deemed to have violated the standard of care for a prescribing practitioner's profession for issuing a prescription for or administering a controlled substance containing an opioid to a patient when the patient and the prescribing practitioner have not executed and filed a voluntary nonopioid directive form under the provisions of this Section.
- H. A prescribing practitioner who willfully fails to comply with a patient's voluntary nonopioid directive form may be subject to disciplinary action pursuant to rules promulgated by his health profession licensing board. (Section added by Act 28 of the 2018 Regular Session)

[End of Subpart D]			
[End of Part I]			
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[End of Subchapter A]			
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[End of Chapter 5-D]			

# Chapter 5-G – Miscellaneous Health Provisions

#### Part VI. Local Option for Control of Mitragynine Speciosa

[This new Part VI, consisting of Sections 1300.51 through 1300.53, was created by Act 416 of the 2023 Regular Session, effective August 1, 2023. Subsequent amendments are noted herein.]

# §1300.51. Short title

This Part shall be known and may be cited as the "Local Option for Mitragynine Speciosa".

# §1300.52. Definitions

As used in this Part, the following terms have the following meanings ascribed to them unless the context clearly indicates otherwise:

- (1) "Local government" means a parish or municipality, as provided pursuant to Article VI, Part I, Sections 1 and 2 of the Constitution of Louisiana.
- (2) "Mitragynine speciosa" shall have the same meaning as defined in R.S. 14:91.10.

# §1300.53. Local government prohibition or regulation

Notwithstanding any other provision of law to the contrary, a local government may enact an ordinance to prohibit the sale or distribution of mitragynine speciosa products or to regulate the sale or distribution of mitragynine speciosa products in a manner that is more restrictive than provided for in R.S. 14:91.10.

[End of Part VI]

\* \* \*

#### Part VIII. Hope for Louisiana Patients

[This new Part VIII, consisting of Sections 1300.71 through 1300.79, was created by Act 750 of the 2024 Regular Session, effective August 1, 2024. Subsequent amendments are noted herein.]

#### §1300.71. Short title

This Part shall be known and may be cited as the "Hope for Louisiana Patients Law".

#### **§1300.72. Definitions**

As used in this Part, the following terms have the meanings ascribed to them:

- (1) "Eligible facility" means an institution that is operating with a Federalwide Assurance for the Protection of Human Subjects, in accordance with 42 U.S.C. 289(a) and 45 CFR Part 46, and an eligible facility that is subject to the Federalwide Assurance for the Protection of Human Subjects laws, regulations, policies, and guidelines, including renewals and updates.
- (2) "Eligible patient" means an individual who meets all of the following conditions:
  - (a) Has considered all other treatment options currently approved by the United States Food and Drug Administration.
  - (b) Has received a recommendation from his physician for an individualized investigational treatment, based on analysis of the patient's genomic sequence, human chromosomes, deoxyribonucleic acid, ribonucleic acid, genes, gene products such as enzymes and other types of proteins or metabolites.
  - (c) Has a life-threatening, severely debilitating illness or serious disease or condition associated with morbidity that has a substantial impact on day-to-day functioning and is attested to by the patient's treating physician.
  - (d) Has given written, informed consent for the use of the investigational drug, biological product, or device.
  - (e) Has documentation from his physician that he meets the requirements of this Part.
- (3) "Individualized investigational treatment" means drugs, biological products, or devices that are unique to and produced exclusively for use for an individual patient, based on his own genetic profile.
  - (a) "Individualized investigational treatment" includes but is not limited to individualized gene therapy antisense oligonucleotides and individualized neoantigen vaccines.
  - (b) "Individualized investigational treatment" does not include any drug, biological product, or device derived from human primary or secondary embryonic stem cells or cell lines, or tissues or cells derived from abortion, but does include any drug, biological product, or device derived from human perinatal tissues, cells, and secreted factors not obtained from an abortion.

- (4) "Life-threatening or severely debilitating illness" has the same meaning as provided in <u>21 CFR 312.81</u>, or any successor law or regulation, as applicable.
- (5) "Written, informed consent" means a written document that is signed by the patient, or if the patient is a minor, by any person authorized to consent in accordance with the Louisiana Medical Consent Law, R.S. 40:1159.1 et seq., and attested to by the patient's physician and a witness and that, at a minimum, includes all of the following:
  - (a) An explanation of the currently approved products and treatments for the illness, disease, or condition from which the patient suffers.
  - (b) An attestation that the patient concurs with his physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life.
  - (c) Clear identification of the specific proposed individualized investigational drug, biological product, or device that the patient is seeking to use.
  - (d) (i) A description of the potentially best and worst outcomes of using the individualized investigational drug, biological product, or device and a realistic description of the most likely outcome.
    - (ii) The description shall include the possibility that new, unanticipated, different, or worse symptoms might result and that death could be hastened by the proposed treatment.
    - (iii) The description shall be based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.
  - (e) A statement that the patient's health plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of the individualized investigational drug, biological product, or device, unless they are specifically required to do so by law or contract
  - (f) A statement that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment with the individualized investigational drug, biological product, or device and that care may be reinstated if this treatment ends and the patient meets hospice eligibility requirements.
  - (g) A statement that the patient understands that he is liable for all expenses consequent to the use of the individualized investigational drug, biological product, or device and that this liability extends to the person's estate, unless a contract between the patient and the manufacturer of the drug, biological product, or device states otherwise.

#### §1300.73. Individualized investigational drugs; facility and manufacturer abilities

- A. A manufacturer operating within an eligible facility and in accordance with all applicable Federalwide Assurance for the Protection of Human Subjects laws and regulations may make available an individualized investigational treatment and an eligible patient may request an individualized drug, biological product, or device from an eligible facility or manufacturer operating within an eligible facility in accordance with this Part. This Part shall not require a manufacturer to make available an individualized investigational drug, biological product, or device to an eligible patient.
- B. An eligible facility or manufacturer operating within an eligible facility may do all of the following:
  - (1) Provide an individualized investigational drug, biological product, or device to an eligible patient without receiving compensation.
  - (2) Require an eligible patient to pay the costs of, or the costs associated with, the manufacture of the investigational drug, biological product, or device.

#### §1300.74. Coverage expansion; permissible; not required

- A. This Part shall not expand the coverage required of an insurer in accordance with any provisions of <u>Title 22</u> of the Louisiana Revised Statutes of 1950.
- B. A health plan, third-party administrator, or governmental agency may provide coverage for the cost of an individualized investigational drug, biological product, or device or the cost of services related to the use of an individualized investigational drug, biological product, or device in accordance with this Part.
- C. This Part shall not require any governmental agency to pay costs associated with the use, care, or treatment of a patient with an individualized investigational drug, biological product, or device.
- D. This Part shall not require a hospital or facility licensed in accordance with R.S. 40:2006(A) and operating or planning to operate within the state to provide new or additional services unless approved by the hospital or facility.

# §1300.75. Patient death; insurance provisions

If a patient's death is proximately caused by treatment with an individualized investigational drug, biological product, or device, the patient's estate, heirs, or devisees are not liable for any debt remaining after payment by insurance for charges directly incurred for the treatment. However, this provision shall not provide an exemption to liability for charges for

non-experimental treatments provided to the patient, including non-experimental treatments rendered to the patient due to complications or consequences of the experimental treatment.

#### §1300.76. Prohibition of actions taken against licensure of healthcare providers

- A. A licensing board or disciplinary subcommittee shall not revoke, fail to renew, suspend, or take any action against a healthcare provider's license issued in accordance with <a href="Chapter 15">Chapter 15</a> of Title 37 of the Louisiana Revised Statutes of 1950 based solely on the healthcare provider's recommendations to an eligible patient regarding access to or treatment with an individualized investigational drug, biological product, or device.
- B. An entity responsible for Medicare certification shall not take action against a healthcare provider's Medicare certification based solely on the healthcare provider's recommendation that a patient has access to an individualized investigational drug, biological product, or device.

# §1300.77. Eligible patient's access to individualized investigational drugs, biological products, or devices

- A. An official, employee, or agent of this state shall not block or attempt to block an eligible patient's access to an individualized investigational drug, biological product, or device.
- B. Providing counseling, advice, or a recommendation consistent with medical standards of care from a licensed healthcare provider shall not be a violation of this Section.

# §1300.78. Prohibition of private causes of action and insurance mandates

- A. This Part shall not create a private cause of action against a manufacturer of an individualized investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient using the individualized investigational drug, biological product, or device for any harm done to the eligible patient resulting from the individualized investigational drug, biological product, or device, if the manufacturer or other person or entity is complying in good faith with the terms of this Part and has exercised reasonable care.
- B. This Part shall not affect any mandatory healthcare coverage for participation in clinical trials in accordance with any provisions provided in <u>Title 22</u> of the Louisiana Revised Statutes of 1950.

# §1300.79. Severability

If one or more provisions of this Part or the application thereof is found to be unconstitutional, the provision shall be declared severable and the balance of this Part shall remain effective notwithstanding such unconstitutionality.

[End of Part VIII]

\* \* \* \*

[End of Chapter 5-G]

\* \* \*

[End of Chapter 5]

# **Chapter 11 – State Department of Hospitals**

#### Part VII. Hospices

[This new Part VII was created by Act 941 of the 1988 Regular Session, effective August 1, 1988. Subsequent amendments are noted herein.]

# §2181. Short title

This Part may be cited as the "Hospice Licensing Law."

\* \* \*

# §2191. Disposal of deceased patient's unused controlled substances

- A. Upon death of a patient receiving hospice services, ownership of the patient's unused Schedule II, III, IV, or V controlled substances under 21 CFR 1308 may transfer to the hospice for immediate disposal pursuant to the following provisions:
  - (1) Each hospice shall establish a written procedure to ensure safe disposal of unused controlled substances by a hospice nurse at the time of a patient's death.
  - (2) Upon the death of a patient receiving hospice services, in the presence of a witness, the hospice nurse shall record in the medical record the name and quantity of each unused controlled substances.
  - (3) (a) The hospice nurse shall conduct immediate disposal of the controlled substance at the site of care by complying with the Environmental Protection Agency and Drug Enforcement Administration guidelines for safe disposal or immediate mail-back to a registered authorized collector pursuant to 21 CFR 1317.40.
    - (b) If conducting immediate disposal at the site of care, the hospice nurse shall perform the disposal in the presence of a witness, who shall sign a document indicating their witnessing the disposal.
    - (c) If participating in immediate mail-back to a registered authorized collector, the hospice nurse shall deposit the unused controlled substance into the mail-back envelope and seal the envelope at the site of care. This shall be done in the presence of a witness, who shall sign a document indicating their witnessing the hospice nurse sealing the controlled substance in the mail-back envelope. The hospice nurse shall immediately initiate its delivery to the registered authorized collector.
  - (4) Hospice employees shall not remove any controlled substances from the site of care, except for the hospice nurse responsible for disposal pursuant to Subparagraph (3)(c) of this Subsection.
  - (5) The hospice nurse shall record the method of disposal in the medical record.
- B. A copy of the written policy established pursuant to this Section shall be furnished to each patient and to the patient's healthcare representative at the time the patient is enrolled in hospice.

(Section added by Act 23 of the 2018 Regular Session)

\* \* \* [End of Part VII]

Part XIII. Provisions Common to Healthcare Facilities and Services

\* \* \*

#### **Subpart B. Healthcare Workplace Violence Prevention**

[This new Subpart B of Part XIII of Chapter 11 of Title 40 was created by Act 461 of the 2022 Regular Session, effective August 1, 2022, consisting of Sections 2199.11 through 2199.19. Subsequent amendments are noted herein.]

#### §2199.11. Purpose

The purpose of this Subpart is to protect public health and safety by establishing policies and practices through which incidents of workplace violence in healthcare settings can be properly addressed, mitigated, and, wherever possible, prevented.

#### **§2199.12.** Definitions

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

- (1) "Department" means the Louisiana Department of Health and any healthcare professional licensing board transferred to and placed within the department pursuant to R.S. 36:259(A).
- (2) "Licensing board" means any board or commission that has the duty to license a regulated entity as defined in this Section.
- (3) "Regulated entity" means any healthcare entity such as a licensed healthcare facility listed in R.S. 40:2006(A)(2), a federally qualified health center as defined in R.S. 40:1183.3, a pharmacy permitted in accordance with Part IV of Chapter 14 of Title 37 of the Louisiana Revised Statutes of 1950, and any office of a healthcare provider that treats patients and such office is not otherwise licensed by the state but provides healthcare services delivered by a licensee of a healthcare professional licensing board created in Title 37 of the Louisiana Revised Statutes of 1950. A healthcare entity shall not be considered a regulated entity if it employs five or fewer licensed medical providers, such as a physician, pharmacist, advanced practice registered nurse, physician assistant, or dentist.
- (4) "Workplace violence" means violent acts, including battery or the intentional placing of another person in reasonable apprehension of sustaining battery, directed toward persons at work or on duty with their employment. (Section amended by Act 624 of the 2024 Regular Session)

# §2199.13. Licensed healthcare facilities; signage addressing workplace violence required

- A. Each regulated entity shall display at its premises at least one sign that conforms with the specifications of Subsection B of this Section and indicates that abuse of or workplace violence against healthcare staff will not be tolerated and could result in a felony conviction under R.S. 14:38 or other applicable criminal laws.
- B. Each sign displayed in accordance with the requirements of this Section shall conform with all of the following specifications:
  - (1) The sign shall be posted in a conspicuous location in a publicly accessible area of the regulated entity's facility.
  - (2) The sign shall be at least eighteen inches tall by eighteen inches wide and written in the English language with letters not less than one square inch in size.

#### §2199.14. Healthcare workplace violence; public information

- A. The department shall develop, publish, and maintain public information regarding the issue of healthcare workplace violence on its website.
- B. The information provided by the department pursuant to this Section shall include, at a minimum, all of the following:
  - (1) A listing of best practices, toolkits, and resources on the issue of healthcare workplace violence from governmental and private authorities including, without limitation, the Occupational Safety and Health Administration and the Joint Commission.
  - (2) Actions that regulated entities can take and policies that such entities can adopt to prevent, respond to, report, and mitigate healthcare workplace violence.
  - (3) A checklist of items for regulated entities to consider when developing a workplace violence prevention plan.
- C. The website on which the department publishes information regarding healthcare workplace violence shall include a downloadable example of text that complies with the provisions of <u>R.S. 40:2199.13(A)</u> relative to signage required to be displayed at facilities of regulated entities.

#### §2199.15. Healthcare workplace violence prevention plans

- A. (1) Each regulated entity shall develop and maintain a workplace violence prevention plan that includes, at a minimum, all of the following resources:
  - (a) Resources for ongoing education on the issue of workplace violence.
  - (b) Resources for prevention of workplace violence.
  - (c) Resources on responding to incidents of workplace violence and debriefing with respect to such incidents and responses thereto.
  - (2) Each healthcare workplace violence prevention plan developed pursuant to this Section shall address and encompass all of the following:
    - (a) Personnel education and policies requiring all healthcare workers who provide direct patient care to patients to receive, at least annually, education and training in a format that provides an opportunity for interactive questions and answers with a person knowledgeable about the workplace violence prevention plan. The education and training delivered pursuant to a workplace violence prevention plan shall cover topics including but not limited to all of the following:

- (i) How to recognize the potential for violence to occur.
- (ii) When and how to seek assistance to prevent or respond to violence.
- (iii) How to report violent incidents to law enforcement.
- (iv) Resources available to employees for coping with incidents of workplace violence.
- (b) A system for responding to and investigating violent incidents and situations involving violence.
- (c) A system for regularly, and not less than annually, assessing and improving upon factors that may contribute to or help in preventing workplace violence. This system shall address, without limitation, all of the following aspects of the workplace:
  - Staffing, including staffing patterns that may contribute to, or be insufficient to address, the risk of violence.
  - (ii) Sufficiency of security systems including alarms, emergency response systems, and availability of security personnel.
  - (iii) Job design, equipment, and facilities.
  - (iv) Security risks associated with particular units of the workplace, areas of the regulated entity's facility with uncontrolled access, late night or early morning shifts, and areas surrounding the facility such as employee parking areas.
- (d) A requirement that the regulated entity maintain and make available to its employees a written safety and security plan.
- B. The department may prescribe additional required content beyond the material required by Subsection A of this Section for workplace violence prevention plans.
- C. Each regulated entity shall orient all permanent and temporary employees of the entity's facility to the workplace violence prevention plan of the entity.
- D. Each regulated entity shall maintain its workplace violence prevention plan in effect at all times.

# §2199.16. Acts of workplace violence at licensed healthcare facilities; reporting required

- A. Each regulated entity shall report to the proper authority, as required by the entity's workplace violence prevention plan, any instance of workplace violence that occurs on its property.
- B. If an instance of workplace violence at a regulated entity's facility results in injury, involves the use of a firearm or other dangerous weapon, or presents an urgent or emergent threat to the welfare, health, or safety of facility personnel, the regulated entity shall report the incident within twenty-four hours.

# §2199.17. Retaliation in connection with reporting healthcare workplace violence; prohibition

- A. No regulated entity shall take any retaliatory action against a person who, in good faith, reports an allegation of or an instance of workplace violence.
- B. No regulated entity shall prohibit an employee from, or take punitive or retaliatory action against an employee for, seeking assignment and intervention from local emergency services or law enforcement when a violent incident occurs.
- C. No regulated entity shall discharge, demote, suspend, threaten, or harass an employee, or discriminate against an employee in the terms and conditions of his employment, because of any lawful act engaged in by the employee, or taken on behalf of the employee, in reporting to law enforcement a crime or allegation involving workplace violence at the regulated entity's facility.
- D. The employee protections provided for in this Section shall be in addition to, and shall not replace, any protections conferred by the provisions of Title 23 of the Louisiana Revised Statutes of 1950.

# **§2199.18.** Enforcement

- A. The department or a licensing board may take action against any licensee it has issued to a regulated entity or an owner of such an entity, up to and including license revocation, to enforce the provisions of this Subpart. The department may make appropriate referrals to other state or federal agencies and offices that may have jurisdiction over workplace violence or retaliation allegations.
- B. With respect to enforcement of this Subpart, the department shall adopt rules and regulations in accordance with the <u>Administrative Procedure Act</u> to provide for all of the following:
  - (1) Penalties associated with violations of particular provisions of this Subpart.
  - (2) Notice to a regulated entity of a violation.
  - (3) An informal reconsideration process.
  - (4) An appeal procedure including judicial review.

**§2199.19. Rulemaking**The department and each licensing board shall promulgate in accordance with the <u>Administrative Procedure Act</u> all such rules as are necessary to implement the provisions of this Subpart.

[End of Part XIII]

[End of Chapter 11]

# **Chapter 36 – Regulation of Pharmacy Benefit Managers**

[This new Chapter 36, composed of Sections 2861 through 2871, was created by Act 124 of the 2019 Regular Session. Section 2869 became effective August 1, 2019; all other sections became effective July 1, 2020. Subsequent amendments are noted herein.]

#### §2861. Legislative intent and public health policy

It is the intent of the legislature that the purpose of this Chapter is to license, permit, and monitor pharmacy benefit managers to provide for the effective control and regulation of their activities, maintain and enforce order regarding the prescribing, dispensing, marketing, selling, managing, and use of prescription drugs in this state, and to protect the health, safety, and general welfare of the citizens and residents of this state.

#### §2862. Short title

This Chapter shall be known and may be cited as the "Pharmacy Benefit Manager Licensing Law".

#### §2863. Definitions

As used in this Chapter, the following definitions shall apply:

- (1) "Attorney general" means the Louisiana attorney general.
- (2) "Beneficiary" means a person who resides or is employed in this state and is covered or is eligible to be covered by a health plan.
- (3) "Board of Pharmacy" means the Louisiana Board of Pharmacy.
- (4) "Commissioner of insurance" means the Louisiana commissioner of insurance.
- (5) "Department of Insurance" means the Louisiana Department of Insurance.
- (6) "Department of Justice" means the Louisiana Department of Justice.
- (7) "Health plan" means an individual or group plan or program which is established by contract, certificate, law, plan, policy, subscriber agreement, or by any other method and which is entered into, issued, or offered for the purpose of arranging for, delivering, paying for, providing, or reimbursing any of the costs of health or medical care, including pharmacy services, drugs, or devices.
- (8) "Pharmacy benefit management plan" and "pharmacy benefits program" mean a plan or program that pays for, reimburses, covers the cost of, or otherwise provides for pharmacist services, drugs, or devices to individuals who reside in or are employed in Louisiana.
- (9) "Pharmacy benefit manager" and "PBM" mean any person or business who administers the prescription drug or device program of one or more health plans on behalf of a third party in accordance with a pharmacy benefit program. This term includes any agent or representative of a pharmacy benefit manager hired or contracted by the pharmacy benefit manager to assist in the administering of the drug program and any wholly or partially owned or controlled subsidiary of a pharmacy benefit manager.

#### §2864. Duties of pharmacy benefit managers

- A. A pharmacy benefit manager shall owe the beneficiaries of any pharmacy benefit management plan administered by the pharmacy benefit manager and to the entities that have entered into a contract with the pharmacy benefit manager the duties of good faith, honesty, trust, confidence, and candor.
- B. The standard for the fulfillment of a pharmacy benefit manager's duties shall be to act with a high degree of care, skill, prudence, and diligence required of a reasonable and prudent person with substantial experience and expertise in the management of pharmacy benefit management plans and payment of claims.
- C. Failure of a pharmacy benefit manager to satisfy the duties established in this Section shall not create a separate or independent cause of action nor shall it be construed to prohibit any cause of action established by or recognized in federal or state law.

# §2865. General licensing and permitting requirements

- A. Every pharmacy benefit manager that does business in this state or pays for benefits for a beneficiary through a pharmacy benefit management plan shall be licensed or permitted as required by this Chapter.
- B. No license or permit shall be issued to a pharmacy benefit manager who has not registered with the Louisiana secretary of state to conduct business within the state.
- C. Each license and permit shall be valid only for the applicant listed on the application.
- D. (1) A pharmacy benefit manager license or permit is not transferable.
  - (2) No license or permit shall be subject to sale, assignment or other transfer, voluntary or involuntary.

- (3) In the event the ownership of the pharmacy benefit manager changes by fifty percent or more after the initial issuance of the license or permit, the ownership shall be deemed sufficiently different as to require a new pharmacy benefit manager license or permit.
- (4) The continued operation of a pharmacy benefit manager under a license or permit issued pursuant to this Chapter after its ownership has changed by fifty percent or more shall constitute sufficient basis for finding that the pharmacy benefit manager is operating in this state without a valid license or permit in violation of this Chapter.

# §2866. General applicability

- A. The licensure and regulation requirements set forth pursuant to this Chapter shall apply generally to any pharmacy benefit manager regardless of plan or benefit financing.
- B. Nothing in this Chapter shall be construed to require coverage of any specific drug in any health plan, but shall apply once a drug is covered or included on a health plan formulary.

# §2867. Pharmacy benefit manager; regulation by commissioner of insurance; applicability of the Louisiana Insurance Code

- A. Every pharmacy benefit manager that does business in this state shall be licensed as required by the <u>Louisiana</u> Insurance Code.
- B. Every pharmacy benefit manager licensed by the commissioner of insurance shall abide by the provisions of the Louisiana Insurance Code and the rules and regulations of the Department of Insurance regarding the pharmacy benefit manager's business regulated by the commissioner of insurance.

# §2868. Pharmacy benefit manager; regulation by Louisiana Board of Pharmacy; requirements for permitting

- A. A pharmacy benefit manager shall obtain and maintain a permit from the Board of Pharmacy if the pharmacy benefit manager administers, develops, maintains, performs, or provides one or more of the following pharmacy services in the state or that affects one or more beneficiaries of a pharmacy benefit management plan administered by the pharmacy benefit manager:
  - (1) Adjudication of appeals or grievances related to prescription drug coverage.
  - (2) Disease management programs. For purposes of this Subsection, "disease management program" means a program adopted to guide and care for beneficiaries with chronic health problems to improve the quality of health care provided to them and prevent future need for medical resources by using an integrated comprehensive approach.
  - (3) Drug formularies. For purposes of this Subsection, "drug formulary" means a list of prescription medications or pharmaceutical products developed and approved by each health plan that may be dispensed to a beneficiary through participating pharmacies. A drug formulary may also be referred to as a "preferred drug list", "prior authorization list", or "pharmacopeia".
  - (4) Drug regimen reviews. For purposes of this Subsection, "drug regimen review" means third-party review of all medications a beneficiary is currently using, whether prescribed or over-the-counter, and administered by any method.
  - (5) Prescription drug management programs. For purposes of this Subsection, "prescription drug management program" means a program developed and designed to administer the prescription drug benefit as part of a health plan, and as part of such administration a PBM may contract with pharmacies for implementation and dispensing drugs in accordance with the program.
  - (6) Processing of prior authorization requests. For purposes of this Subsection, "processing of prior authorization requests" means making a determination regarding payment coverage based on an advance approval request submitted by a physician or other healthcare provider before a specific procedure, service, device, supply, or medication is delivered to the beneficiary.
  - (7) Quality care dosing services. For purposes of this Subsection, "quality care dosing services" means electronically checking prescription medications before they are filled at the pharmacy to ensure that the quantity and dosage is consistent with the recommendations of the United States Food and Drug Administration and others.
  - (8) Step therapy procedures. For purposes of this Subsection, "step therapy procedure" means protocols and policies that establish a specific sequence in which prescription drugs for a medical condition are approved for coverage by a health plan for a beneficiary which generally requires cheaper drugs to be used before more costly drugs. Step therapy may also be referred to as "fail first" protocol.
  - (9) Utilization management and utilization reviews. For purposes of this Subsection, "utilization management" and "utilization review" mean third-party review and approval of appropriateness and necessity of care that

- a healthcare provider has indicated for a beneficiary prior to delivery and coverage of such care.
- (10) Any other act, service, operation, or transaction incidental to or forming a part of the compounding, filling, dispensing, exchanging, giving, offering for sale, or selling drugs, medicines, poisons, or devices in this state by pharmacists or pharmacies, pursuant to a prescription or an order of physicians, dentists, veterinarians, or other licensed practitioners, requiring, involving, or employing the science or art of any branch of the pharmacy profession, study, or training.
- B. Every pharmacy benefit manager permitted by the Board of Pharmacy shall abide by the applicable provisions of the Louisiana Pharmacy Practice Act and the rules and regulations of the Board of Pharmacy.
- C. (1) A pharmacy benefit manager may file for a hearing conducted before an independent third-party adjudicator with the division of administrative law upon notice from the board that it intends to take adverse or disciplinary action against the pharmacy benefit manager that may result in the suspension or termination of the pharmacy benefit manager's permit. If the pharmacy benefit manager elects to file for a hearing with the division of administrative law, the ruling of the administrative law judge shall be appealable by either the pharmacy benefit manager or the board, whichever party does not prevail.
  - (2) Nothing in this Subsection shall be construed to prevent the pharmacy benefit manager from proceeding with a hearing before the board as provided for in the <u>Administrative Procedure Act</u>, nor shall anything in this Subsection be construed to prevent the board from taking any other action provided for by law or rule that would not result in suspension or termination of the pharmacy benefit manager's permit.

(Section amended by Act 536 of the 2022 Regular Session)

# §2869. Pharmacy benefit manager monitoring advisory council; membership; functions

- A. There is hereby created a pharmacy benefit manager monitoring advisory council, referred to hereafter in this Chapter as the "advisory council", that shall consist of the following members, each of whom may appoint a designee:
  - (1) The commissioner of the Department of Insurance.
  - (2) The president of the Louisiana State Board of Medical Examiners.
  - (3) The president of the Louisiana Board of Pharmacy.
  - (4) The attorney general.
  - (5) The director of the public protection division of the Department of Justice.
  - (6) The secretary of the Louisiana Department of Health.
  - (7) The president of the Louisiana Academy of Physician Assistants.
  - (8) The president of the Louisiana State Medical Society.
  - (9) The president of the Louisiana Association of Nurse Practitioners.
  - (10) The president of the Louisiana Pharmacists Association.
  - (11) The president of the Louisiana Independent Pharmacies Association.
  - (12) The president of the National Association of Chain Drug Stores.
  - (13) The president of the Pharmaceutical Research and Manufacturers of America.
  - (14) The president of the Louisiana Academy of Medical Psychologists.
  - (15) The president of the Louisiana Association of Health Plans.
  - (16) The president of a pharmacy benefit manager licensed by the Louisiana Board of Pharmacy, selected by the Louisiana affiliate of the Pharmaceutical Care Management Association from a list of interested and qualified individuals.
  - (17) The president of the Louisiana Association of Business and Industry.
  - (18) The chief executive officer of the Louisiana Business Group on Health.
  - (19) The president of the Louisiana AFL-CIO.
  - (20) The president of the Louisiana Association of Health Underwriters.
  - (21) The governor.
  - (22) The chairman of the House Committee on Insurance.
  - (23) The chairman of the Senate Committee on Insurance.
  - (24) The chairman of the House Committee on Health and Welfare.
  - (25) The chairman of the Senate Committee on Health and Welfare.
- B. The members of the advisory council shall serve at the pleasure of their respective appointing authorities. Seven members shall constitute a quorum for the transaction of all business. The members shall elect a chairman and vice chairman whose duties shall be established by the advisory council. The member elected to serve as chairman shall fix a time and place for regular meetings of the advisory council, which shall meet at least quarterly. The advisory council shall establish policies and procedures necessary to carry out its duties. Expenses for the administrative staffing of the advisory council shall be provided for from the licensing fees paid by pharmacy benefit managers and may be transferred between state agencies by memorandum of understanding or cooperative endeavor agreement.

- C. The commissioner of insurance and the Board of Pharmacy may utilize the full advisory council or individual member agency expertise for the purpose of investigating a complaint against a pharmacy benefit manager or conducting an audit of a pharmacy benefit manager. In exercising the authority provided for in this Subsection, the same provisions of confidentiality applicable to the Department of Insurance and Louisiana Board of Pharmacy during an investigation shall apply to the advisory council or individual member agencies whose expertise is being utilized. The advisory council may meet in executive session, as necessary, to discuss matters involving an active investigation.
- D. The advisory council shall provide monitoring of pharmacy benefit managers in Louisiana to advise the legislature, commissioner of insurance, and Board of Pharmacy on the most effective and efficient manner of regulation of pharmacy benefit managers to ensure the protection of the public. Any licensed pharmacy benefit manager operating in the state of Louisiana shall provide full cooperation with the advisory council on matters including but not limited to those set forth in Subsection E of this Section.
- E. The advisory council shall advise on matters including but not limited to the licensure and regulation of pharmacy benefit managers set forth in this Title and Titles <u>22</u> and <u>37</u> of the Louisiana Revised Statutes of 1950, applicable rules and regulations of state agencies, and federal laws or rules relative to pharmacy benefit managers.
- F. The advisory council may conduct and its members may attend and participate in a meeting via electronic means in accordance with R.S. 42:17.2.

(Section amended by Act 723 of the 2022 Regular Session)

# §2870. Prohibited acts; unfair and deceptive trade practices

- A. A pharmacy benefit manager in Louisiana shall not:
  - (1) Commit any unfair and deceptive trade practice prohibited by <u>R.S. 22:1964(15)</u>.
  - (2) Perform any act that violates the duties, obligations, and responsibilities imposed under the Louisiana Insurance Code on a pharmacy benefit manager.
  - (3) Buy, sell, transfer, or provide personal healthcare or contact information of any beneficiary to any other party for any purpose with one exception. A pharmacy benefit manager may provide such information regarding beneficiaries of a health plan to that health plan if requested by the health plan provider.
  - (4) Conduct or participate in spread pricing, as defined in <u>R.S. 22:1863(9)</u> without providing the notice required by R.S. 22:1867.
  - (5) (a) Directly or indirectly engage in patient steering to a pharmacy in which the pharmacy benefit manager maintains an ownership interest or control without making a written disclosure and receiving acknowledgment from the patient. The disclosure required by this Paragraph shall provide notice that the pharmacy benefit manager has an ownership interest in or control of the pharmacy, and that the patient has the right under the law to use any alternate pharmacy that they choose. The pharmacy benefit manager is prohibited from retaliation or further attempts to influence the patient, or treat the patient or the patient's claim any differently if the patient chooses to use the alternate pharmacy.
    - (b) The provisions of this Paragraph shall not apply to employers, unions, associations, or other persons who employ, own, operate, control, or contract directly with a pharmacy or pharmacist for the purpose of managing or controlling prescription costs paid for the benefit of an employee or member or those covered by the employee or member's plan, or when the persons contract with a pharmacy benefit manager to steer employees or members to pharmacists or pharmacies which the person owns, operates, or controls.
  - (6) (a) Penalize a beneficiary or provide an inducement to the beneficiary for the purpose of getting the beneficiary to use specific retail, mail order pharmacy, or another network pharmacy provider in which a pharmacy benefit manager has an ownership or controlling interest or that has an ownership or controlling interest in a pharmacy benefit manager.
    - (b) For purposes of this Paragraph, "inducement" means the providing of financial incentives, including variations in premiums, deductibles, copayments, or coinsurance.
    - (c) The provisions of this Paragraph shall not apply to employers, unions, associations, or other persons who employ, own, operate, control, or contract directly with a pharmacy or pharmacist for the purpose of managing or controlling prescription costs paid for the benefit of an employee or member or those covered by the employee or member's plan, or when the persons contract with a pharmacy benefit manager to steer employees or members to pharmacists or pharmacies which the person owns, operates, or controls.
  - (7) Retroactively deny or reduce a claim of a pharmacist or pharmacy for payment or demand repayment of all or part of a claim after the claim has been approved by the pharmacy benefit manager as authorized by R.S. 22:1856.1.
  - (8) Reimburse a local pharmacist or local pharmacy, as defined in <u>R.S. 46:460.36(A)</u>, less than the amount it reimburses chain pharmacies, mail-order pharmacies, specialty pharmacies, or affiliates of the pharmacy

benefit manager for the same drug or device or for the same pharmacy service in this state.

- (9) Fail to update prices as required by R.S. 22:1857.
- (10) (a) Fail to honor maximum allowable cost (MAC) prices as set forth in R.S. 22:1863 et seq.
  - (b) A pharmacy benefit manager shall not require a pharmacist or pharmacy to purchase drugs from any particular wholesaler. However, if a pharmacy benefit manager recommends or provides a wholesaler, then that wholesaler must be willing and able to honor the pharmacy benefit manager's MAC price, ship the order, and have receipt of the order within two business days with no additional charge to the pharmacist.
  - (c) The wholesaler with the lowest prices, which is listed as the MAC price, is not obligated to sell or ship to a nonmember pharmacist or pharmacy. If the wholesaler chooses not to sell the drug to the pharmacist or pharmacy, then the MAC price set by the pharmacy benefit manager must be adjusted to the price available to the pharmacist or pharmacy through another wholesaler.
- (11) Fail to meet the payment standards established in R.S. 22:1856.
- (12) Fail to provide detailed remittance advice to pharmacists and pharmacies in compliance with R.S. 22:1856.
- (13) (a) Fail to pay any state or local sales tax imposed on any drug, device, or pharmacy services or to remit the sales tax to the appropriate pharmacist or pharmacy for the tax proceeds to be forwarded to the sales tax authority.
  - (b) A pharmacy benefit manager who does not pay the sales tax shall be liable to the taxing authority for the tax, interest, penalties, and any other fees or costs imposed by law for failure to pay sales taxes.
  - (c) No pharmacy benefit manager shall deduct the taxes from any amount due to a pharmacist or pharmacy for a drug, device, or pharmacy service or charge or pay anyone a fee or surcharge for paying any sales tax or remitting any sales tax proceeds to a pharmacist or pharmacy if that fee or surcharge would be imposed directly or indirectly on the pharmacist or pharmacy.
  - (d) All pharmacy benefit managers who pay any out-of-state pharmacist or pharmacy for drugs or devices shipped to a beneficiary in this state or for pharmacy services rendered to a beneficiary which is taxable in this state shall remit the tax directly to the appropriate taxing authority.
  - (e) Any pharmacist or pharmacy who does not receive sales tax proceeds from a pharmacy benefit manager for any drug, device, or pharmacy service which is subject to sales taxes shall have no responsibility for payment of the taxes if the pharmacist or pharmacy provides written notification to the appropriate taxing authority, the Department of Insurance, and the Board of Pharmacy of the pharmacy benefit manager's failure to remit the sales taxes at the time the next sales tax return is due to be filed.
  - (f) State or local sales taxes and other applicable state-imposed taxes or fees shall be considered as part of the allowable cost and shall be included in the claim submitted by a pharmacist or pharmacy.
- (14) Restrict early refills on maintenance drugs to an amount less than seven days for a prescription of at least a thirty-day supply. However, at the direction of the Louisiana Department of Health, for purposes of administering the Medicaid pharmacy benefit program, a pharmacy benefit manager may apply a more restrictive early refill policy without violating the provisions of this Paragraph.
- (15) Require a beneficiary to follow a plan's step therapy protocol if the prescribed drug is on the health plan's prescription drug formulary, the beneficiary has tried the step therapy required prescription drug while under his current or previous health plan, and the provider has submitted a justification and supporting clinical documentation that such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse effect or event.
- (16) Delay a decision on a request for authorization to dispense a prescription drug for more than seventy-two hours, or twenty-four hours in exigent circumstances in which the patient, in the opinion of the prescribing provider, pharmacy, or pharmacist submitting the authorization request, is suffering from a health condition that may seriously jeopardize the patient's life, health, or ability to regain maximum function. A request for authorization shall include relevant data or appropriate documentation to render a decision on a request for authorization.
- (17) Exploit prescription drug information obtained from beneficiaries for monetary gain or economic power over beneficiaries, pharmacists, or pharmacies.
- (18) Sell, exchange, or use in any manner prescription drug information regarding a beneficiary obtained through a beneficiary's use of a prescription for purposes of marketing, solicitation, consumer steering, referral, or any other practice or act, except as otherwise provided for in this Section, that provides the pharmacy benefit manager or any of its affiliates or subsidiaries economic power or control over pharmacists or pharmacies or interfere in the free choice of a beneficiary.
- (19) Engage in drug repackaging and markups. A pharmacy benefit manager that owns or controls a mail-order pharmacy shall not allow the mail-order pharmacy to repackage drugs and sell the repackaged items at higher prices than the original average wholesale price unless beneficiaries who may buy the repackaged

- drugs are informed in writing that the drugs have been repackaged and are being sold at the higher price.
- (20) Operate in Louisiana without either being registered with and in good standing with the Louisiana secretary of state to do business in Louisiana or being licensed by and in good standing with the commissioner of insurance, as provided by this Chapter.
- B. (1) The commission of any of the acts or any combination of the acts prohibited by this Section shall be considered an unfair method of competition and unfair practice or act in accordance with the Unfair Trade Practices and Consumer Protection Law, <u>R.S. 51:1401</u> et seq., if the violations are committed or performed with such frequency as to indicate a general business practice. Notwithstanding any provision of law to the contrary, the private right of action created by <u>R.S. 51:1409</u> shall not apply to this Section.
  - (2) For purposes of this Section, a violation shall be considered to have occurred each time a prohibited act is committed.
  - (3) Each day that a pharmacy benefit manager operates without being registered with and in good standing with the secretary of state to do business in Louisiana or without being licensed by and in good standing with the commissioner of insurance, as provided by this Chapter, shall be considered a separate violation.
- C. (1) Nothing in this Section shall be construed to interfere with or violate a consumer's right to know where the consumer may have access to the lowest cost drugs, whether a consumer is utilizing insurance or other third-party reimbursement or not.
  - (2) Nothing in this Section shall be construed to interfere with the requirement that consumers receive notice of changes to pharmacy networks, such as the inclusion of new pharmacies or removal of existing pharmacies from networks.

#### §2871. Enforcement

- A. Notwithstanding any provision of law to the contrary, enforcement of the Pharmacy Benefit Manager Licensing Law shall be conducted in accordance with the following requirements:
  - (1) (a) The commissioner of insurance shall be responsible for investigation and enforcement of the provisions of the <u>Louisiana Insurance Code</u>, the applicable provisions of this Chapter, and any rules or regulations promulgated by the Department of Insurance relative to pharmacy benefit managers. The commissioner shall refer any complaint he believes to be outside of his jurisdiction to the Board of Pharmacy or the Louisiana Department of Justice.
    - (b) The commissioner of insurance may suspend or revoke a pharmacy benefit manager's permit, license, or registration in accordance with the <u>Louisiana Insurance Code</u> and the rules and regulations promulgated by the Department of Insurance relative to pharmacy benefit managers.
  - (2) (a) The Board of Pharmacy shall be responsible for investigation and enforcement of the provisions of the Louisiana Pharmacy Practice Act, the applicable provisions of this Chapter, and any rules or regulations promulgated by the Board of Pharmacy relative to pharmacy benefit managers. The Board of Pharmacy shall refer any complaint it believes to be outside of its jurisdiction to the Department of Insurance or the Louisiana Department of Justice.
    - (b) Upon completion of a complaint investigation or compliance audit, and after notice and an opportunity for an adjudicatory hearing held in accordance with the <u>Administrative Procedure Act</u>, the Board of Pharmacy may suspend, revoke, or place on probation a license, permit, or registration issued to the pharmacy benefit manager or any entity in which the pharmacy benefit manager has an ownership or controlling interest, or take any other action authorized by the <u>Louisiana Pharmacy Practice Act</u> or the rules and regulations of the Board of Pharmacy.
- B. (1) The commissioner of insurance and the Board of Pharmacy shall be responsible for conducting random compliance audits, which may be desk audits based on data provided by the pharmacy benefit manager, to ensure compliance with this Chapter.
  - (2) A pharmacy benefit manager doing business in Louisiana shall make itself open and available to comply with compliance audit data requests.
- C. On the first day of each month, the Board of Pharmacy shall submit to the attorney general a report of complaints received against pharmacy benefit managers and the date that each complaint was received during the prior calendar month in a format prescribed by the attorney general. The report shall include a cumulative list of all complaints received against pharmacy benefit managers until final disposition.
- D. Nothing in this Section shall be construed as a limitation on the attorney general's power to enforce the Unfair Trade Practices and Consumer Protection Law, R.S. 51:1401 et seq., or to limit his authority in any way under that law, or as a limitation on the attorney general's power to negotiate and enter into a stipulation with a pharmacy benefit manager. Furthermore, nothing in this Section shall prohibit the Board of Pharmacy from referring a complaint or audit finding to the Louisiana Department of Justice.

#### [End of Chapter 36]

\* \* \*

[End of Title 40]

\* \* \*

[End of Louisiana Revised Statutes]

# Louisiana Administrative Code

#### **Title 46 – Professional and Occupational Standards**

#### Part LIII: Pharmacists

#### **Chapter 1. Introduction**

# §101. Preamble

A. Pursuant to the authority granted by <u>R.S. 37:1182</u>, and in the interest of promoting the public health, safety, and welfare, the following rules and regulations are hereby adopted by the Louisiana Board of Pharmacy (board).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2075 (October 2003), effective January 1, 2004.

#### §103. Pharmacy Board Organization

#### A. Board Officers

- 1. President. The president shall preside at all board meetings.
- 2. Vice-Presidents. In the absence of the president, the vice-presidents shall preside in descending order at all board meetings.
- 3. Secretary. The secretary shall conduct the nomination procedure for board candidates and report the results of the balloting to the governor for his appointments.

#### B. Election

- 1. General Election. The board shall annually elect officers from its membership.
- 2. Special Election. The president may call a special election of the board to fill vacancies of elected officers.
- C. Officers' Terms. Officers elected by the board shall serve one-year terms and their terms shall end upon the election of their successors. An officer elected to a vacant position shall serve for the remainder of that term, at which time an election shall occur commensurate with the annual election.
- D. Per Diem. A per diem, as authorized by <u>R.S. 37:1178</u>, is defined as compensation to be received by a board member for each day of service while attending regular or called board meetings, while attending to official business of the board, or while attending a board related or board sanctioned conference, including travel days for members to and from these meetings, conferences, and related business. This per diem shall not serve as reimbursement for meals, lodging, and other expenses incurred as a result of these meetings, conferences, and related business.
- E. Board Budget. The board is a self-sustaining body that shall generate sufficient revenues funded by fees, appropriations, and/or assessments in order to maintain efficient operations.
  - 1. Administrative Costs. The board may assess administrative costs as it deems necessary to facilitate the proper implementation of its rules and regulations.
  - 2. Annual Operating Budget. The board has the responsibility to perfect an annual operating budget.
  - 3. Annual Capital Budget. The board has the responsibility to establish a capital budget, when applicable.
- F. Executive Director. The executive director shall carry out functions of the board relative to its statutory requirements and other duties as defined by the board. With the board's approval, the executive director serves as the appointing authority and may appoint additional employees for professional, clerical, and special duties necessary to carry out the board's functions and may establish standards for the conduct of employees.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2075 (October 2003), effective January 1, 2004.

#### §105. Board Procedures

- A. All board procedures and operations shall adhere to the Administrative Procedure Act, <u>R.S. 49:950</u> *et seq.*, the Open Meetings Law, R.S. 42:4.1 *et seq.*<sup>1</sup>, and the Public Records Act, <u>R.S. 44:1</u> *et seq.*
- B. Order. Robert's Rules of Order shall govern all proceedings unless otherwise provided.
- C. Public Comments. A public comment period shall be held during each board meeting.
  - 1. Persons desiring to present public comments shall notify the board chairman or executive director no later than the beginning of the meeting. However, to assure that an opportunity is afforded to all persons who desire to make public comments, the chairman shall inquire at the beginning of the meeting if there are

additional persons who wish to comment. The chairman shall allot the time available for the public comments in an equitable manner among those persons desiring to comment, limiting each person to a maximum of three minutes, with the total comment period not to exceed 30 minutes. Each person making public comments shall identify himself and the group, organization, company, or entity he represents, if any.

2. Unless otherwise provided by law, public comment is not part of the evidentiary record of a hearing or case unless sworn, subject to cross-examination, offered by a party as relevant testimony, and received in accordance with the Administrative Procedure Act, R.S. 49:950 et seq.

#### D. Open Meetings via Electronic Means

- 1. Disability Accommodations
  - a. People with disabilities are defined as any of the following:
    - A member of the public with a disability recognized by the <u>Americans with Disabilities Act</u> (ADA);
    - ii. A designated caregiver of such a person; or
    - iii. A participant member of the board with an ADA-qualifying disability.
  - b. The written public notice for an open meeting, as required by <u>R.S. 42:19</u>, shall include the name, telephone number, and email address of the board representative to whom a disability accommodation may be submitted.
  - c. The designated board representative shall provide the requestor with an accommodation, including the teleconference and/or video conference link, for participation via electronic means as soon as possible following receipt of the request, but no later than the start of the scheduled meeting.
  - d. Participation via electronic means shall count for purposes of establishing quorum and voting.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2076 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 50:1155 (August 2024).

#### §107. Board Committees and Subcommittees

- A. Board committees are working bodies created by the board comprising members appointed or removed by the president to address and deliberate specific pharmacy matters referred by the board for specified periods consisting of the following:
  - 1. Standing Committees. Standing committees are permanent bodies and are created by the board comprising members appointed by the president with the duty to address and deliberate specific subject matters referred by the board.
  - 2. Special Committees. Special committees are appointed by the president for a particular period to address or deliberate special matters.
  - 3. Board Subcommittees. Board subcommittees are created by the board comprising members and ex-officio non-voting members appointed by the president that are ancillary to a standing or special committee to address or deliberate a limited committee subject matter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2076 (October 2003), effective January 1, 2004.

#### §109. Standing Board Committees

- A. Executive Committee. The executive committee, comprised of the president, vice-presidents, and secretary shall function to address interim administrative board matters that require immediate attention between regularly scheduled board meetings.
- B. Regulation Revision Committee. The regulation revision committee, consisting of at least three board members appointed at the discretion of the president, shall function to preliminarily draft rules, regulations, and policies to be considered by the full board for promulgation and/or resolution or order.
- C. Reciprocity Committee. The reciprocity committee, consisting of at least three board members appointed at the discretion of the president, shall function to document the qualifications, compliance, and credentials of reciprocity candidates.
- D. Impairment Committee. The impairment committee, consisting of at least three board members appointed at the discretion of the president, shall function to study, recognize, address the need to identify, and monitor the recovery of impaired persons in order to protect the public and the practitioner. Additionally, the impairment

- committee shall function to investigate, review, and interview impaired or allegedly impaired persons practicing or assisting in the practice of pharmacy and tender findings and recommendations to the board.
- E. Violations Committee. The violations committee shall consist of at least three board members appointed at the discretion of the president. Board-designated staff shall preliminarily determine the disposition of complaints and alleged offenses. Thereafter, the violations committee shall function to receive complaints, receive staffs' reports, and evaluate and review findings. The disposition of alleged offenses shall be determined by conducting an informal inquiry conference, an interlocutory hearing, and/or referring the matter to special counsel for formal hearing by the full board.
- F. Reinstatement Committee. The reinstatement committee, consisting of at least three board members appointed at the discretion of the president, shall function to receive complaints, receive staffs' reports, evaluate and review findings, interview applicants, deliberate, and tender recommendations to the full board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2076 (October 2003), effective January 1, 2004.

# §111. Official Journal

A. The official journal of the board is the *Louisiana Board of Pharmacy Newsletter*. The newsletter may be used in administrative hearings as proof of notification to pharmacists, interns, pharmacy technicians, pharmacy technician trainees, and holders of pharmacy permits.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

#### §113. Rulemaking Procedures

- A. Petitions from Interested Persons
  - 1. All petitions, whether requesting the adoption, amendment, or repeal of a rule shall be submitted in written form on plain white bond paper which is letter size (8 ½" by 11"). The text shall be framed with a margin of at least one inch on all sides, shall have a pitch of not less than 10 characters per inch, and shall be double-spaced; provided however that quotations may be single-spaced as may other matter customarily presented in that manner.
  - 2. The petition shall include the name, address, telephone number and email address of the petitioner as well as any organization the petitioner represents.
  - 3. The petition shall explain the reason(s) for the requested action as well as what results would be expected from such action. The petition shall provide an estimate of the revenues and expenditures expected if the requested action is adopted.
  - 4. The petition shall be considered by the board at its next regular meeting provided the complete petition is received at least 30 days prior to that meeting.
- B. Board Initiatives
  - 1. The board may refer topics to the Regulation Revision Committee, either during a board meeting or through the president in the interim between board meetings.
- C. Administrative Procedures Act
  - 1. When the board approves a regulatory proposal for rulemaking, the board shall comply with the Administrative Procedures Act at R.S. 49:950 et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 49:953.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 46:586 (April 2020).

#### §115. Fees

b.

- A. The fees charged and collected by the board shall not be less nor more than the following schedule:
  - 1. Credentialing Fees for Persons
    - a. Pharmacy Technician Candidate

i.	Application fee for new pharmacy technician candidate registration	\$ 50.00
Phan	macy Technician	
i.	Application fee for new pharmacy technician certificate	\$ 100.00
ii.	Certificate renewal fee, per year	\$ 60.00
iii.	Delinquent renewal fee, per year (50 percent of renewal fee)	\$ 30.00
iv.	Reinstatement fee for lapsed, suspended, or revoked certificate	\$ 200.00

	c.	Pharmacy Intern		
		i. Application fee for new pharmacy intern registration	\$	50.00
	d.	Pharmacist		
		i. Application fee for new pharmacist license		300.00
		ii. Application fee for transfer of pharmacist license		150.00
		iii. License renewal fee, per year		150.00
		iv. Delinquent renewal fee, per year (50 percent of renewal fee)	\$	75.00
		v. Reinstatement fee for lapsed, suspended, or revoked license		200.00 100.00
2.	Cre	vi. Pharmacy education support fee, per year dentialing Fees for Businesses	Ф	100.00
۷.	a.	Pharmacy		
	u.	i. Application fee for new pharmacy permit	\$	500.00
		ii. Application fee for change of location of pharmacy permit		200.00
		iii. Pharmacy permit renewal fee, per year		200.00
		iv. Delinquent renewal fee for pharmacy permit, per year (50 percent of		
		renewal fee)	\$	100.00
		v. Application fee for new controlled dangerous substance (CDS) license for		
		pharmacy	\$	25.00
		vi. CDS license renewal fee, per year	\$	25.00
		vii. Delinquent renewal fee for CDS license, per year (50 percent of	Ф	10.50
		renewal fee)	\$	12.50
		viii. Application fee for new emergency drug kit (EDK) permit	\$	50.00
		ix. EDK permit renewal fee, per year	\$	50.00 150.00
		<ul><li>x. Application fee for new automated medication system (AMS) registration</li><li>xi. AMS registration renewal fee, per year</li></ul>		150.00
		xii. Application fee for new sterile compounding pharmacy permit		500.00
		xiii. Sterile compounding pharmacy permit renewal fee, per year		500.00
		xiv. Reinstatement fee for lapsed, suspended, or revoked pharmacy permit,	Ψ	300.00
		CDS license, EDK permit, AMS registration, or sterile compounding		
		pharmacy permit	\$	200.00
		xv. Pharmacy education support fee, per year	\$	100.00
	b.	Durable Medical Equipment Provider		
		i. Application fee for new durable medical equipment (DME) permit	\$	200.00
		ii. DME permit renewal fee, per year	\$	200.00
		iii. Delinquent renewal fee for DME permit, per year (50 percent of	Φ	100.00
		renewal fee)	\$	100.00
		iv. Reinstatement fee for lapsed, suspended, or revoked DME permit	\$ \$	200.00 100.00
	0	v. Pharmacy education support fee, per year	Ф	100.00
	C.	Pharmacy Benefit Manager i. Application fee for new pharmacy benefit manager (PBM) permit	\$	500.00
		ii. PBM permit renewal fee, per year	\$	500.00
		iii. Delinquent renewal fee for PBM permit, per year (50 percent of	Ψ	500.00
		renewal fee)	\$	250.00
3.	Fee	s for Products and Services		
	a.	Products		
		i. Pharmacist certificate	\$	75.00
		ii. Pharmacist silver certificate	\$	100.00
		iii. Louisiana Pharmacy Law Book	\$	40.00
		iv. Official list of licensees, per credential type	\$	150.00
		v. Photocopies of documents, per page	\$	0.50
	b.	Services	Φ	250.00
		i. Administrative hearing fee	\$	250.00
		ii. Certification of credential	\$	20.00
		<ul><li>iii. Certification of practical experience to another jurisdiction</li><li>iv. Certification of document as true copy or office record</li></ul>	\$ \$	25.00 5.00
		v. Handling and mailing, per page	\$	1.00
4.	Boa	ard member per diem, per day	\$	75.00
		1, t/	~	

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182(A)(21).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 48:1901 (July 2022).

# [End of Chapter 1]

Note:

1 The legislature relocated the Open Meetings Law to  $\underline{R.S. 42:11}$  et seq. in 2010. The board has not yet revised Section 105 to update the citation.

# **Chapter 3. Board Hearings**

# §301. Board Hearing Procedures and Jurisdiction

- A. Person. The board has jurisdictional authority over the person practicing pharmacy, assisting in the practice of pharmacy, operating a pharmacy, or otherwise licensed, registered, certified, or permitted by the board. A person is as defined in R.S. 37:1164(33) of the Pharmacy Practice Act.
- B. Subject Matter. The board has jurisdiction over any subject matter related to the practice of pharmacy or any other matter regarding the dispensing or selling of prescription drugs in a safe manner so as not to endanger the public health, safety, or welfare.
- C. Board Authority. The board has authority to adopt rules pursuant to the Pharmacy Practice Act, <u>R.S. 37:1161</u> et seq., and the Administrative Procedure Act, <u>R.S. 49:950</u> et seq., regarding due process disciplinary hearings.
- D. Venue. A due process hearing shall convene in a designated Louisiana parish at a regularly called board meeting.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

## §303. Summons

- A. A summons shall represent a complaint of an alleged violation directed to a respondent.
- B. Hearing Notice. The board shall initiate a hearing by issuing a notice summons. The notice summons shall be forwarded to the respondent commanding his presence to appear before the board for a due process hearing setting forth the following:
  - 1. Name. The notice shall include the respondent's name and address.
  - 2. Time. The notice shall state the designated time, date, and place.
  - 3. Allegation. The notice shall recite the alleged violation(s) establishing a cause of action and the nature of the hearing.
  - 4. Authority. The notice shall make references to specific board, state, or federal statutes, regulations, rules, policies, or code of ethics involved in the alleged violation(s).
  - 5. Citation. The notice shall cite legal or jurisdictional authority constituting an alleged violation(s).
  - 6. Documents. The notice may include supporting documents, reports, and/or other relevant material.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

# §305. Service

- A. Method. Service of a summons shall be made either by regular, registered, or certified mail, with a return receipt requested, or board or court designated process servers confected by tendering the summons to the respondent personally or domiciliary at the last known address.
- B. Time. Service shall be made at least thirty days prior to the date of the hearing as per R.S. 37:1245.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1245.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

# §307. Default Proceedings

A. The board may proceed with a hearing in the event the respondent fails to appear after due notice was perfected or a diligent effort had been made to perfect service on the respondent at the last known address of record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

# §309. Joinder

A. Several complaints may be joined or incorporated and the respondents may be joined in the same or similar complaints based on the same or similar acts or transactions that are connected in a common plan or scheme.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

## §311. Consolidation

A. Hearings may be held jointly to assure a fair due process hearing. Any alleged violations may be consolidated for an administrative hearing of respondents.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

## §313. Severance

A. A severance of complaints is permitted when a fair due process hearing will not be satisfied. Otherwise, complaints may be heard jointly.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2077 (October 2003), effective January 1, 2004.

# §315. Motions

- A. Hearing Motions. Motions are directed to the board or presiding officer for particular relief or action before, during, or after a hearing and shall be in writing when applicable, and allege specifically the grounds upon which the relief is based, and filed with the board five days before hearing or within 10 days post-hearing or timely filed during the hearing. At an appropriate time to be decided by the hearing officer, oral or written motions may be directed to the presiding hearing officer during a hearing. Hearing motions are directed to the presiding hearing officer and disposed of appropriately.
- B. Continuance Motions.
  - 1. Postponement Motions. The board may grant or deny a continuance based upon critical or extenuating circumstances that could jeopardize a fair and expeditious due process hearing.
  - Time. Continuance motions shall be filed in writing at least five days prior to the scheduled hearing with specific grounds for postponement. This requirement may be waived by the board under emergency circumstances.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

#### §317. Recusation

- A. A board member or special counsel may be recused by one's own motion because of an inability to contribute to a fair and impartial hearing or may be recused by a majority vote of the board members present based on the following grounds:
  - 1. prejudicial or personal interest in a case that might prevent one from participating in an impartial hearing.
  - 2. the board may recuse the presiding administrative hearing officer on his own motion or he may be disqualified upon his own inability to contribute to or conduct an impartial hearing by the respondent filing an affidavit of specific grounds at least five days prior to the scheduled hearing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

#### §319. Sequestration

A. Upon request by either respondent or special counsel or by direction of the hearing officer, witnesses shall be sequestered and not allowed in the hearing chambers or permitted to discuss their testimony with other witnesses.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

## §321. Sanction Guidelines

- A. The sanctions imposed by the board pursuant to <u>R.S. 37:1241</u> of the Pharmacy Practice Act shall be based on the following guidelines:
  - 1. Nature. The nature or seriousness of the violation.
  - 2. Degree. The degree of culpability, knowledge and/or intent, or the responsibility to have knowledge.
  - 3. Scope. The scope of circumstances involved.
  - 4. Demeanor. Honesty and truthfulness of respondent.
  - 5. History. History of prior offenses.
  - 6. Sanctions. Prior sanctions.
  - Cooperation. Willingness of respondent to comply with applicable laws and regulations and avoid future violations.
  - 8. Sufficiency. Sanctions are sufficient to remedy the problem.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

# §323. Administrative Investigation

- A. Upon the receipt of a written complaint, board staff shall initiate and conduct an investigation.
  - 1. Grounds. The investigative report shall be reviewed by board-designated staff and forwarded to the violations committee or legal counsel to determine sufficient grounds for proceeding either informally or formally.
  - 2. The report shall include:
    - a. respondent's name and address;
    - b. a concise statement of facts and circumstances indicating the basis of the routine or specific complaint or cause of action; and
    - c. supporting documents and/or materials.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

## §325. Violations Committee

- A. Purpose. Board-designated staff shall receive reports and complaints and review and evaluate findings to determine the nature and disposition of the alleged violation(s). The alleged violation(s) may then be directed to:
  - 1. violations committee for informal hearing;
  - 2. violations committee for interlocutory hearing; and/or
  - 3. special counsel for institution of a formal administrative hearing.
- B. Guidelines. If determined appropriate by board-designated staff, the violations committee shall receive and review complaints and determine the disposition of the pending matters based on the following:
  - 1. Seriousness. The seriousness of the alleged offense.
  - 2. Degree. The extent of the alleged violations.
  - 3. History. The history of prior violations.
  - 4. Record. Prior sanctions.
  - 5. Cooperation. Willingness to obey the prescribed laws and regulations.
  - 6. Deterrent. Consider the sanctions as a deterrent to future violations.
  - 7. Remedy. The sanctions are sufficient to remedy the problem.
- C. Informal Hearings. The violations committee may conduct an informal non-adversarial hearing with the respondent properly noticed of the inquiry regarding the issues to be discussed. The committee shall receive information and deliberate as to a cause of action regarding a potential violation. The committee may recommend a course of action to the full board or dismiss the allegations by an affirmative majority vote of the committee. Should the violations committee recommend a course of action to the full board, the following shall apply:
  - 1. Disclosure. Respondent's testimony or the work product from the informal hearing of any staff or committee member may not be introduced at any subsequent formal hearing.
  - 2. Recusal. Violations committee members shall not be permitted to participate in subsequent formal board hearings pertaining to complaints or alleged violations heard by the violations committee, unless respondent allows otherwise.

- D. Interlocutory Hearings. By interlocutory (or summary) hearing, the violations committee may summarily suspend a license, permit, certification, and/or registration prior to a formal administrative board hearing wherein, based upon the committee's judgment and reflected by adequate evidence and an affirmative majority decision, a person poses a danger to the public's health, safety, and welfare, and the danger requires emergency action.
  - 1. Summons Notice. A summary proceeding summons notice shall be served at least five days before the scheduled hearing to afford the respondent an opportunity to be heard with respect to a potential summary suspension action. The notice shall contain a time, place, nature, and the grounds asserted relative to the alleged conduct warranting summary suspension.
  - 2. Burden of Proof. Legal counsel shall have the burden of proof to support the contention that the public's health, safety, or welfare is in danger and requires summary or emergency action.
  - 3. Evidence. The respondent shall have the right to appear personally and/or be represented by counsel to submit affidavits, documentary evidence, or testimony in response to the cause of action asserted as the basis for the summary suspension.
  - 4. Decision. The committee shall determine whether to grant or deny the summary suspension based upon adequate evidence with an affirmative majority vote substantiated by finding(s) of fact and conclusion(s) of law that the public's health, safety, or welfare is in danger and requires emergency or summary action.
  - 5. Report. The committee shall submit their findings and interlocutory decree to the board when rendered.
  - 6. Suspensive Duration. The summary suspension decree shall be followed by a formal administrative hearing within 30 days from receipt of notice by the respondent.
- E. Probation Violation Hearings. Probation violation proceedings shall be initiated upon receipt of information indicating that a respondent is in violation of any of the terms or conditions of his probation.
  - Review. Board-designated staff shall receive and review the compliance officer's report and then
    determine whether a probation violation proceeding is warranted. Should a probation violation hearing be
    determined warranted, the violations committee shall proceed by interlocutory hearing or informal
    hearing as deemed appropriate.
  - 2. Notice. Notice shall be afforded the respondent of the allegation(s) forming the basis of the alleged violation status, and the time and place of the appropriate hearing to be conducted.
  - 3. Disposition. Disposition of the hearing shall be according to the appropriate procedures to informal hearings or interlocutory hearings.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2078 (October 2003), effective January 1, 2004.

#### §327. Impairment Committee

- A. Impairment. Impairment means a condition that causes an infringement on the ability of an individual to practice, or assist in the practice of, pharmacy sufficient to pose a danger to the public. Impairment may be caused by, but is not limited to, alcoholism, substance abuse or addiction, mental illness, or physical illness.
- B. The impairment committee shall have the following responsibilities:
  - 1. supervise the Practitioner Recovery Program.
  - 2. recommend for board consideration any addictionists or other professionals utilized by the program.
  - 3. recommend for board consideration any action for reinstatement of recovering persons.
  - 4. any other related responsibilities deemed appropriate by the board.
- C. Practitioner Recovery Program. The board may establish and maintain a recovery program to assist impaired persons through the recovery process so that they may safely return to practice. The board may utilize the services of outside agencies to assist in the recovery of the impaired person.
- D. Informal Hearing.
  - 1. The board may convene an informal administrative hearing to identify an impaired person and to take appropriate action. The board may require the appearance of any persons deemed necessary to properly conduct an informal hearing. This process shall be conducted by the impairment committee chairman or any other member(s) of the board or staff as the president deems necessary.
  - 2. Any knowledge acquired by any board member or staff in identifying and assisting an allegedly impaired person shall not automatically be grounds for recusal at any later hearing on that same matter.
  - 3. An impaired or allegedly impaired person may enter into a preliminary consent agreement that shall include a mandatory surrender of that person's license, permit, certification, or registration, which shall be delivered to the board office and shall effectively prohibit that person from practicing, or assisting in the practice of, pharmacy. Such person shall agree to enter into an approved treatment and monitoring program as determined by the board. This consent agreement shall not restrain the board from conducting

- violations proceedings in the matter as it deems necessary.
- 4. The impairment committee may make recommendations to the full board and/or the violations committee as it deems appropriate on an impaired or allegedly impaired person.
- E. Impaired Reinstatement. An application for reinstatement of an impaired person shall be filed with the impairment committee for consideration and recommendation to the violations committee and/or the full board.
  - 1. An impaired person may petition the board for reinstatement of his license, permit, certification, or registration, provided he has:
    - a. documented proof from an attending physician that he has successfully completed an alcohol or substance abuse recovery program; and
    - b. a current post-treatment evaluation from a board-approved addictionist; and
    - successfully completed any requirements the board deems necessary with respect to the particular type of impairment.
    - d. the impairment committee may waive the above requirements for impairments not related to alcohol or substance abuse.
  - 2. After the above stipulations have been met, the person applying for reinstatement may be scheduled for an interview with the impairment committee for consideration of any recommendation to the reinstatement committee and/or the full board.
  - 3. Upon reinstatement, the board may place the reinstated person on probation for a specified length of time and may assign conditions of the probation.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2079 (October 2003), effective January 1, 2004.

## §329. Formal Hearing

- A. Authority. The board shall provide a formal administrative hearing pertaining to the proprietary rights or privilege to practice pharmacy, or operate a pharmacy, or hold a certificate or registration, in accordance with the Administrative Procedure Act, <u>R.S. 49:950</u> *et seq.*, with authority to take disciplinary action pursuant to R.S. 37:1241 of the Pharmacy Practice Act.
- B. Ex-Parte Communication. Once a formal hearing has been initiated and notice served, board members participating in the decision process shall not communicate with a respondent or a respondent's attorney concerning any issue of fact or law involved in the formal hearing.
- C. Notice. A formal disciplinary public proceeding may be initiated upon proper notice to a respondent and held at a designated time and place based upon the following grounds:
  - 1. violation sufficient evidence or a serious complaint of an alleged violation to require a formal hearing shall be directed to legal or special counsel for administrative prosecution to justify a formal hearing; or
  - 2. failure to respond a failure by the respondent to respond to the violations committee informal inquiry; or
  - 3. irresolvable issues a violations committee informal hearing fails to resolve all issues and requires further formal action; or
  - 4. irreconcilable issues an interlocutory hearing fails to resolve all pertinent pending issues thus requiring further formal action; or
  - 5. reaffirmation reaffirmation of an interlocutory decree; or
  - 6. requirement a formal administrative hearing requirement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2080 (October 2003), effective January 1, 2004.

# §331. Formal Hearing Procedures

- A. Hearing Officers.
  - 1. Administrative Hearing Officer. The presiding hearing officer may be the board president, a vice-president, or other individual appointed by the president or his successor. The hearing officer has the responsibility to conduct a fair and impartial proceeding with the administrative duty and authority to:
    - a. convene an administrative board hearing;
    - b. rule on motions and procedural questions arising during the hearing such as objections or admissibility of evidence or examination of witnesses;
    - c. issue or direct staff to issue subpoenas;
    - d. declare recess;

- e. maintain order;
- f. enforce a standard of conduct to insure a fair and orderly hearing;
- g. remove disruptive person(s) from a hearing.
- 2. Oaths. The presiding hearing officer, executive director, or other board designee may administer oaths.
- B. Administrative Jury. The board, comprised of a quorum of members, shall serve as an administrative jury to hear and determine the disposition of the pending matter based on the finding(s) of fact and conclusion(s) of law by receiving evidence and reaching a decision and/or ordering sanctions with an affirmative majority record vote of board members participating in the decision process.
- C. Administrative Hearing Clerk. The board's executive director shall serve as the administrative hearing clerk and shall maintain administrative hearing records.
- D. Administrative Prosecutor. The legal or special counsel shall prosecute the pending matter and bear the burden of proof to be presented to the board.
- E. Administrative Reporting. The board-designated stenographer shall record all testimony dictated and evidence received at the hearing. The utilization of recording equipment may be employed.
- F. Hearing Order.
  - 1. Docket. Contested matters shall be identified by reference docket number and caption title. The administrative hearing clerk or other staff or board member designated by the presiding hearing officer shall announce the docket and identify persons present or absent in the hearing chambers.
  - 2. Complaint. The complaint may be read at an open hearing unless waived by the respondent.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2080 (October 2003), effective January 1, 2004.

## §333. Pre-Hearing Conference

A. Respondents and/or their legal counsel in matters pending before the board may be directed by the presiding administrative hearing officer to appear at a pre-hearing conference to consider the simplification of the issues, admission of facts, or stipulations to documents which may avoid unnecessary proof and such other items as may aid in the disposition of the matter(s) pending.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

#### §335. Consent Agreements

A. Respondents may enter into consent agreements with the board on any matter pending before the board. A consent agreement is not final until the board approves the consent agreement by majority vote of the administrative jury. If the consent agreement is rejected in full or part, the matter shall be heard at the next regularly scheduled board hearing. However, nothing herein shall limit the board from modifying a consent agreement, with respondent's approval, to include less severe sanctions than those originally agreed to in a pending consent agreement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

#### §337. Opening Statement

A. An opening statement by legal or special counsel may present a brief position comment with an outline of evidence to be offered. Respondent or respondent's legal counsel may present an opening defense position statement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

# §339. Evidence

A. Testimony Received. Testimony shall be received under oath administered by the presiding hearing officer, the executive director, or other staff or board member designated by the hearing officer.

- B. Evidence Introduction. All parties shall be afforded an opportunity to present evidence on all issues of fact and argue on all issues of law and respond by direct testimony, followed with cross examination as may be required for a full and true disclosure of the facts. The direct presentation of evidence shall be introduced by the legal or special counsel and shall be followed by the respondent in proper person or by legal counsel by direct and/or cross-examination and/or rebuttal.
- C. Examination. Witnesses may be directly examined and cross-examined. Additionally, witnesses and/or respondents may be questioned during an administrative hearing by members of the administrative jury on matters for clarification.
- D. Rule Interpretation. Liberal rules of evidence shall be employed by the presiding hearing officer to provide adequate facts and law necessary for the board to deliberate and decide each case. The board's administrative hearing shall not be bound to strict rules of evidence.
- E. Admissibility. Admissibility of evidence and testimony shall be determined by the presiding hearing officer as provided by law.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

# §341. Closing Arguments

A. Closing arguments may be made by respondent in proper person or by legal counsel followed by closing arguments from prosecuting legal or special counsel.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

## §343. Board Decisions

- A. The board's decision shall be based on finding(s) of fact and conclusion(s) of law. The board's decision shall be based on a preponderance of the evidence presented at a formal hearing, together with the board's determination of any appropriate sanctions, by an affirmative majority record vote of the board members participating in the decision process. Decisions shall be recorded and made part of the record.
  - 1. Board Order. The board's order shall be rendered at the open hearing or taken under advisement and rendered within 30 days of the hearing and then served personally or domiciliary at the respondent's last known address by regular, registered, or certified mail, or by a diligent attempt thereof.
  - 2. Finality of Board Order. The board's order becomes final eleven days after receipt of notification of the board's decision by respondent, provided an appeal is not filed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004, amended LR 33:1124 (June 2007).

## §345. Complaint Dismissal

A. The board, in their discretion and based upon lack of evidence, may orally dismiss at an open hearing a pending matter or parts thereof.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

# §347. Transcripts

A. A complete record of all formal hearing proceedings shall be transcribed, maintained, and available upon written request with sufficient costs of the preparation of the transcript for a minimum of three years from the date the pertinent order(s) is final.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

# §349. Contempt

A. A failure of a respondent or witness to comply with a board order, after being duly served, constitutes contempt and the board may petition a court of competent jurisdiction to rule the witness or respondent in court to show cause why he should not be held in contempt of court.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2081 (October 2003), effective January 1, 2004.

#### §351. Administrative Review

- A. Rehearing. An aggrieved respondent may file within 10 days a rehearing motion in proper form requesting reconsideration or a rehearing by the board or by the interlocutory hearing panel.
- B. Grounds. The board or an interlocutory hearing panel may reconsider the motion for rehearing at the next regularly scheduled board meeting. The grounds for such action shall be either that:
  - 1. the board's decision was clearly contrary to the law or evidence; or
  - 2. newly discovered evidence not available at the time of the hearing which may be sufficient to reverse the board's decision; or
  - 3. issues not previously considered ought to be examined; or
  - 4. it is in the public interest to reconsider the issues and the evidence.
- C. Time. The board or the hearing officer shall grant or deny the petition for rehearing within 30 days after its submission.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004, amended LR 33:1124 (June 2007).

## §353. Judicial Review

A. An aggrieved respondent may appeal the board's decision to a court of appropriate jurisdiction within 30 days from the board order or rehearing motion denial.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1248.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

#### §355. Reporting

A. The board may publish in the board's newsletter the sanctions imposed by the board that are of public interest and the public's right to know.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

# §357. Reinstatement

A. An application for reinstatement based on revocation or suspension of a pharmacist license, pharmacy permit, certification, registration, or any other designation authorized by the board shall be filed with and heard by the reinstatement committee for consideration and recommendation to the full board. The board may then hold a formal hearing whereby the burden of proof shifts to the applicant to demonstrate and support with substantial evidence respondent's rehabilitation and that the reinstatement of the license, permit, certification, registration, or other board-authorized designation at issue would not pose a danger to the public's health, safety, or welfare.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

# §359. Declaratory Statements & Advisory Opinions

A. The board may issue declaratory rulings in accordance with the Administrative Procedure Act, <u>R.S. 49:950</u> et seq. These may include a declaratory statement or an advisory opinion, in the form of a ruling which has the same status as board decision in adjudicated cases, in response to a request for clarification of the effect of

rules and regulations or of R.S. 37:1161 et seq. Advisory opinions as a statement of the board's ruling are generally rendered in cases that relate to specific situations. Declaratory statements contain the board's ruling relative to the petition, with the principles and rationale that support the ruling. Declaratory statements are generally rendered in situations that relate to widespread situations. Neither an advisory opinion nor a declaratory statement has the binding force of law, but they represent the board's expert opinion relative to the matter in question.

- B. A request for a declaratory statement or for an advisory opinion is made in the form of a petition to the board. At a minimum, the petition shall include:
  - 1. the name and address of the petitioner;
  - 2. specific reference to the statutes or rules and regulations to which the petition relates;
  - 3. a concise statement of the manner in which the petitioner is aggrieved by the rule, regulation, or statute, or by its potential application to the petitioner, or in which the petitioner is uncertain of its effects;
  - 4. a statement of whether an oral hearing is desired; and
  - 5. other information appropriate for the board's deliberation on the request.
- C. Said petition shall be considered by the board at its next regularly scheduled meeting provided that the petition has been filed at least 60 days prior to the next scheduled board meeting.
- D. The declaratory statement/advisory opinion of the board on said petition shall be in writing and mailed to petitioner at the last address furnished to the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004.

## §361. Cease and Desist Orders; Injunctive Relief

- A. The board is empowered to issue an order to any person or firm engaged in any activity, conduct, or practice constituting a violation of the <u>Louisiana Pharmacy Practice Act</u> or the regulations promulgated thereto, directing such person or firm to forthwith cease and desist from such activity, conduct, or practice.
- B. If the person or firm to whom the board directs a cease and desist order does not cease and desist the prohibited activity, conduct, or practice within the timeframe directed by said order, the board may seek, in any court of competent jurisdiction and proper venue, a writ of injunction enjoining such person or firm from engaging in the activity, conduct, or practice.
- C. Upon proper showing of the board that such person or firm has engaged in the prohibited activity, conduct, or practice, the court shall issue a temporary restraining order restraining the person or firm from engaging in unlawful activity, conduct, or practices pending the hearing on a preliminary injunction, and in due course a permanent injunction shall be issued after a hearing, commanding the cessation of the unlawful activity, conduct, or practices complained of.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1124 (June 2007).

[End of Chapter 3]

## **Chapter 5. Pharmacists**

# Subchapter A. Licensure Procedures

# §501. Application

A. An application for initial pharmacist licensure, whether by examination or reciprocity, shall be submitted, with appropriate fee, to the board. An application shall expire one year after the date of receipt in the board office.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2082 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 50:390 (March 2024).

## §503. Examination

- A. Examination. A board-approved licensure examination shall consist of integrated pharmacy subject matters and any other disciplines the board may deem appropriate in order to demonstrate competence. An applicant shall achieve a passing score, as determined by the board, in the pharmacy examination.
- B. Re-Examination. In the event the candidate fails the examination, the candidate may repeat the examination in compliance with the test administrator's policy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2083 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:574 (April 2020).

# §505. Licensure

- A. The board shall issue a license upon payment of appropriate fees when the board is satisfied the applicant is competent to practice pharmacy in the state.
  - 1. Renewal. The board shall make the annual pharmacist license renewal application available to all currently licensed Louisiana pharmacists prior to November 1. The completed application along with the appropriate fee shall be submitted to the board by December 31 of each year. A renewal of licensure shall serve as proof of licensure and a pharmacist's license to practice pharmacy for that year of issuance.
    - a. Active. A pharmacist applicant shall pay the annual renewal fee, attain minimum continuing pharmacy education (CPE) as required, and complete and submit the annual renewal form to the board office before December 31 of each year.
    - b. Inactive. A pharmacist applicant may make a written request for inactive status from the board. The inactive pharmacist must complete the annual renewal form furnished by the board and submit it with the appropriate fee to the board before December 31 of each year. An inactive pharmacist shall not engage in the practice of pharmacy and is not required to obtain CPE. In order to upgrade an inactive license to active status, an inactive pharmacist shall petition the board and meet requirements of the reinstatement committee and the board. The board shall set the requirements necessary to assure competency for each individual applying for active status.
  - 2. Expired License. A pharmacist license that has not been renewed by December 31 of each year shall expire and be null and void. The holder of an expired license may submit a written request, complete with any supporting documentation, for reinstatement to the board. The request may be referred preliminarily to the board's reinstatement committee for an informal hearing and recommendation that may be considered by the board at its next regularly scheduled meeting. The board may reinstate an expired license upon payment of applicable annual, delinquent, and lapsed license fees pursuant to R.S. 37:1184<sup>1</sup>, as amended, and other conditions as the board deems appropriate.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2083 (October 2003), effective January 1, 2004, LR 33:1124 (June 2007), LR 38:1234 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:1227 (September 2020).

# §506. Preferential Licensing Procedures for Military-Trained Applicants and Their Dependents

A. Definitions. The following terms shall have the meaning ascribed to them in this Subsection:

Dependent – a resident spouse or resident unmarried child under the age of 21 years, a child who is a student under the age of 24 years and who is financially dependent upon the parent, or a child of any age who is disabled and dependent upon the parent.

Jurisdiction – any state or territory of the United States of America.

*Military* – the armed forces or reserves of the United States, including the Army, Navy, Marine Corps, Coast Guard, Air Force, and the reserve components thereof, the National Guard of any state, the Military Reserves of any state, or the naval militia of any state.

- B. Eligibility. The following persons are eligible for the preferential licensing procedures provided by this Section:
  - 1. a member of the military who has been assigned to duty in Louisiana or his dependent;
  - 2. a civilian employee of the United States Department of Defense who has been assigned to duty in Louisiana or his dependent;
  - 3. a member of the military or civilian employee of the United States Department of Defense or their dependents who have established this state as their state of legal residence in their military record.
- C. Requirements. Eligible persons seeking preferential licensing procedures shall demonstrate compliance with the following requirements:
  - 1. the applicant holds a current and valid pharmacist license in another jurisdiction;
  - 2. the applicant has held the license in the other jurisdiction for at least one year;
  - 3. the applicant has satisfied all educational and experiential requirements required by the pharmacy regulatory authority in the other jurisdiction;
  - 4. the applicant is held in good standing by the pharmacy regulatory authority in the other jurisdiction, or in the event such status is not used in this jurisdiction, the applicant holds an unrestricted license in that jurisdiction;
  - 5. the applicant does not have a disqualifying criminal record as determined by the board;
  - 6. the applicant has not had an occupational license revoked by a board in another jurisdiction due to negligence or intentional misconduct related to the applicant's work in the occupation in another jurisdiction;
  - 7. the applicant has not surrendered an occupational license due to negligence or intentional misconduct related to the applicant's work in the occupation in another jurisdiction;
  - 8. the applicant does not have a complaint, allegation, or investigation pending before a pharmacy regulatory authority in another jurisdiction which relates to unprofessional conduct or an alleged crime. If the applicant has a complaint, allegation, or investigation pending, the board shall not issue or deny a license until the complaint, allegation, or investigation is resolved, or the applicant otherwise satisfies the criteria for licensure in this state to the satisfaction of the board.
  - 9. the applicant has paid all applicable fees in this state.
  - 10. the applicant has applied for a permanent pharmacist license in this state. In the event the applicant fails to qualify for a permanent license as determined by the board, the special work permit issued under the authority of Subsection E of this Section shall be automatically terminated.
- D. Upon receipt of an application for pharmacist licensure by an eligible applicant, the board staff shall mark the application for priority processing and preserve that status until the license is issued, or in the alternative, the board gives notice of its intent to deny the application and refuse to issue the license. The board shall notify the applicant of its licensing decision within 30 calendar days after receiving an application.
- E. In the event the applicant intends to practice pharmacy before the issuance of the permanent license, the board may issue a special work permit to the applicant.
  - 1. The special work permit shall expire 120 days after the date of issue and the permit shall not be renewable.
  - 2. The special work permit shall identify the applicant, and further, shall indicate the authority for that person to practice pharmacy within the state of Louisiana as well as the dates of issue and expiration of the credential.
  - 3. No applicant may practice pharmacy prior to the issuance of a special work permit or pharmacist license, or with an expired special work permit or pharmacist license.
  - 4. The special work permit shall not be eligible for license transfer or reciprocity to any other jurisdiction.
  - 5. The provisions of this Section shall not apply to a member of the military who has received, or is in the process of receiving, a dishonorable discharge from the military. Further, the provisions of this Section shall not apply to the spouse of a member of the military who has received, or is in the process of receiving, a dishonorable discharge from the military.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:3650.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:3075 (November 2013), amended by the Department of Health, Board of Pharmacy, LR 47:244 (February 2021).

## §507. Continuing Education Program

A. The board, recognizing that professional competency is a safeguard for the health, safety, and welfare of the public, shall require continuing pharmacy education as a prerequisite for annual licensure renewal for pharmacists.

#### B. Definitions.

- 1. *ACPE* Accreditation Council for Pharmacy Education.
- 2. *CPE* continuing pharmacy education, a structured postgraduate educational program for pharmacists to enhance professional competence.
- 3. <u>CPE Monitor</u> a collaborative service from the National Association of Boards of Pharmacy (NABP) and the Accreditation Council for Pharmacy Education (ACPE) that provides an electronic system for pharmacists and pharmacy technicians to record and track their completed CPE activities.
- 4. *CPE Unit* a standard of measurement adopted by the ACPE for the purpose of accreditation of CPE programs. One CPE unit is equivalent to 10 credit hours.

#### C. Requirements.

- 1. A minimum of 1 1/2 ACPE or board-approved CPE units, or 15 hours, shall be required each year as a prerequisite for pharmacist licensure renewal. Of this number, no less than 3/10 ACPE or board-approved CPE units, or three hours, shall be acquired through live presentations, as designated by ACPE or the board. Alternatively, should a pharmacist choose to not acquire at least 3/10 ACPE or board-approved CPE units, or three hours, through live presentations, then he shall acquire an additional 5/10 ACPE or board-approved CPE units, or five hours, through any other acceptable method, over and above the minimum requirement, for a total of two ACPE or board-approved CPE units, or 20 hours.
- 2. Pharmacists shall maintain individual records of personal CPE activities with CPE Monitor and shall authorize the board's access to their file by recording their Louisiana pharmacist license number within that file, and shall present a copy of their CPE Monitor transcript when requested by the board.
- 3. When deemed appropriate and necessary by the board, some or all of the required number of hours may be mandated on specific subjects. When so deemed, the board shall notify all licensed pharmacists prior to the beginning of the year in which the CPE is required.
- 4. When deemed appropriate and necessary by the board, the number of hours to be acquired through live presentations as designated by ACPE or the board may be increased. When so deemed, the board shall notify all licensed pharmacists prior to the beginning of the year in which the CPE is required.

#### D. Compliance.

- 1. Complete compliance with CPE rules is a prerequisite for pharmacist licensure renewal.
- 2. Non-compliance with the CPE requirements shall be considered a violation of <u>R.S. 37:1241</u>(A)(2), and shall constitute a basis for the board to refuse licensure renewal.
- 3. The failure to maintain an individual record of personal CPE activities, or falsification of CPE documents, shall be considered a violation of R.S. 37:1241(A)(22).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1306 (October 1997), LR 29:2083 (October 2003), effective January 1, 2004, LR 33:1125 (June 2007), amended by the Department of Health, Board of Pharmacy, LR 46:569 (April 2020).

# §508. Preferential Licensing Procedures for Dependents of Healthcare Professionals Relocating to Louisiana

#### A. Definitions

- 1. As used in this Section, the following terms shall have the meaning ascribed to them in this Subsection: *Dependent* any of the following who relocates to Louisiana with a healthcare professional:
  - i. the healthcare professional's spouse;
  - ii. the healthcare professional's unmarried child under the age of 21 years;
  - iii. the healthcare professional's child who is a student under the age of 24 years and who is financially dependent upon the healthcare professional;
  - iv. the healthcare professional's child of any age who is disabled and financially dependent upon the healthcare professional.

*Healthcare Professional* – a person who provides healthcare or professional services in Louisiana as a physician, physician assistant, dentist, registered or licensed practical nurse or certified nurse assistant, advanced practice registered nurse, certified emergency medical technician, paramedic, certified

registered nurse anesthetist, nurse practitioner, respiratory therapist, clinical nurse specialist, pharmacist, physical therapist, occupational therapist, licensed radiologic technologist, chiropractor, or licensed clinical laboratory scientist; and further, has relocated to and established his legal residence in Louisiana, holds a valid license to provide healthcare services in Louisiana, and is providing healthcare services in Louisiana.

- B. Upon receipt of an application for pharmacist licensure by a dependent of a healthcare professional, the board staff shall mark the application for priority processing and preserve that status until the license is issued, or in the alternative, the board gives notice of its intent to deny the application and refuse to issue the license. The board shall notify the applicant of its licensing decision within 30 calendar days after receiving a complete application.
- C. In the event the applicant intends to practice pharmacy before the issuance of the pharmacist license, the board shall issue a special work permit to the applicant.
  - 1. The special work permit shall identify the applicant and shall indicate the authority for that person to practice pharmacy within the state of Louisiana as well as the dates of issue and expiration of that permit.
  - 2. The special work permit shall expire 120 days after the date of issue and that permit shall not be renewable.
  - 3. No applicant may practice pharmacy prior to the issuance of the special work permit or pharmacist license, or with an expired special work permit or expired pharmacist license.
  - 4. The special work permit shall not be eligible for license transfer or reciprocity to any other jurisdiction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1751.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 49:66 (January 2023).

# §509. Address Change

A. A licensed pharmacist shall notify the board within 10 days, with documentation, attesting to any change of mailing and/or home address. This documented notice shall include the pharmacist's full name and license number, and the old and new address.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2083 (October 2003), effective January 1, 2004.

#### §511. Employment Change

A. A licensed pharmacist shall notify the board within 10 days, with documentation, attesting to any change in employment. This documented notice shall include the pharmacist's full name and license number, the name and address of old and new employment, and the permit numbers of those pharmacies involved.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2084 (October 2003), effective January 1, 2004.

# §514. Impairment

- A. *Impairment* or *Impaired* a condition that causes an infringement on the ability of a person to practice, or assist in the practice, of pharmacy sufficient to pose a danger to the public. *Impairment* may be caused by, but is not limited to, alcoholism, substance abuse or addiction, mental illness, or physical illness.
- B. Pharmacists shall be non-impaired.
- C. Pharmacists who have knowledge another pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician candidate is impaired shall notify the board of that fact as soon as possible.
- D. Pharmacists may be subject to a medical evaluation for impairment by a board-approved addictionist, as authorized by the Louisiana Pharmacy Practice Act, R.S. 37:1161 et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1125 (June 2007).

#### **Subchapter B. Professional Practice Procedures**

#### §515. Prospective Drug Utilization Review

A. A pharmacist shall review the patient record and each prescription presented for dispensing for purposes of enhancing pharmacy care and therapeutic outcomes by recognizing the following potential situations:

- 1. drug over-utilization or under-utilization;
- 2. therapeutic duplication;
- 3. drug-disease contraindications;
- 4. drug-drug interactions;
- 5. inappropriate drug dosage or treatment duration;
- 6. drug-allergy interactions; or
- 7. clinical abuse/misuse.
- B. Upon recognizing any of the above situations, the pharmacist, using professional judgment, shall take appropriate actions.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2084 (October 2003), effective January 1, 2004.

# §517. Patient Counseling

- A. Patient counseling means the effective communication by a pharmacist of information to the patient or caregiver, in order to ensure proper use of drugs and devices.
- B. Minimum Requirements. At a minimum, the pharmacist should be convinced that the patient or caregiver is informed of the following:
  - 1. name and description of the medication;
  - 2. dosage form, dosage, route of administration, and duration of therapy;
  - 3. special directions and precautions for preparation, administration, and use by the patient;
  - 4. common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required in the event of their occurrence;
  - 5. techniques for self-monitoring drug therapy;
  - 6. proper storage of the medication;
  - 7. prescription refill information, if any; and
  - 8. the action to be taken in the event of a missed dose.
- C. The pharmacist may supplement oral information with written information, but shall not use written information alone to fulfill the counseling requirement.
- D. Patient Information.
  - 1. The pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:
    - a. name, address, and telephone number;
    - b. date of birth (or age) and gender;
    - c. allergies/drug reactions, disease state(s); and
    - d. current list of all medications.
- E. Communication to the Patient.
  - 1. A pharmacist shall counsel the patient or caregiver "face-to-face" when possible or appropriate. If it is not possible or appropriate to counsel the patient or caregiver "face-to-face", then a pharmacist should counsel the patient or caregiver by using alternative methods. The pharmacist shall exercise his professional judgment in the selection of alternative methods, including but not limited to, telephonic or electronic communication with the patient or caregiver.
  - 2. A pharmacist shall provide patient counseling to patients discharged from hospitals and/or other institutions, where applicable. However, counseling shall not be required for inpatients of a hospital or institution where a nurse or other licensed health care professional is authorized to administer medication(s).
  - 3. The pharmacist shall maintain appropriate patient-oriented drug information materials for use by the patient upon request.
- F. Waiver. No pharmacist or pharmacy may solicit or encourage blanket waivers for patient counseling. However, nothing in this regulation shall prohibit the patient or caregiver from declining patient counseling.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2084 (October 2003), effective January 1, 2004.

## §519. State of Emergency

A. When the Governor issues, or renews, a state of emergency pursuant to the Emergency Assistance and Disaster Act of 1993, R.S. 29:721 et seq. or a state of public health emergency pursuant to the Louisiana Health Emergency Powers Act, R.S. 29:760 et seq.:

- A pharmacist may dispense an emergency prescription of up to a 90-day supply of a prescribed medication if:
  - a. in the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy; and
  - b. the pharmacist makes a good faith effort to reduce the information to a written prescription marked "emergency prescription", then file and maintain the prescription as required by law.
- 2. A pharmacist not licensed in Louisiana, but currently licensed in another state, may dispense prescription medications in the affected parish(es) during the time a state of emergency exists when:
  - a. the pharmacist has some type of identification to verify current unrestricted licensure in another state;
  - b. the pharmacist has obtained a special work permit from the board;
  - c. the pharmacist is engaged in a legitimate relief effort during the emergency period; and
  - d. the pharmacist and pharmacy notify the board of their presence and approximate location in the affected parish or parishes prior to the engagement of professional practice.
- B. The authority provided for in this Section shall cease with the termination of the state of emergency.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2085 (October 2003), effective January 1, 2004, LR 33:1125 (June 2007), amended by the Department of Health, Board of Pharmacy, LR 47:592 (May 2021)..

# §521. Administration of Medications

- A. Education and Training Required; Supervision
  - 1. Pharmacists who intend to administer medications to their patients shall obtain the education and training described within this Section prior to engaging in such activity.
  - 2. Pharmacists who intend to supervise other pharmacy personnel who administer medications to patients shall obtain the education and training described within this Section prior to engaging in such activity
- B. Education, Training and Continuing Competency
  - 1. A pharmacist who intends to administer medications to patients shall possess a pharmacist license in active status. In the event the license is lapsed, suspended, or in any other inactive status, the pharmacist shall not administer medications. A pharmacist with a license in restricted status may administer medications unless the restriction imposed by the board prevents such activity.
  - 2. The pharmacist shall successfully complete a certificate program for medication administration which is an evidence-based didactic course that meets current Centers for Disease Control and Prevention (CDC) training guidelines. The certificate program shall be acquired from a provider accredited by ACPE, or in the alternative, by Joint Accreditation (JA), and further, the certificate program shall provide a minimum of 20 hours of instruction and experiential training in the following content areas:
    - a. standards for medication administration practices;
    - b. basic immunology;
    - c. recommended medication administration schedules;
    - d. vaccine storage and management;
    - e. informed consent;
    - f. physiology and techniques for medication administration;
    - g. pre- and post-administration assessment and counseling;
    - h. medication administration record management; and
    - i. management of adverse events, including identification and appropriate response, as well as documentation and reporting.
  - 3. The pharmacist shall complete a life safety certification by the American Heart Association through its Basic Life Support (BLS) CPR and AED Training for Healthcare Professionals course, or its successor, or through an equivalent course sponsored by an alternative vendor. The pharmacist may substitute the Advanced Cardiac Life Support (ACLS) course for the BLS standard; however, the Heartsaver CPR and AED or other courses intended for the general public shall not be sufficient to meet this standard. The pharmacist shall renew their certification prior to the expiration date assigned by the course provider.
  - 4. To maintain continuing competency for medication administration, the pharmacist shall acquire at least one hour of continuing pharmacy education per year related to this topic. Continuing pharmacy education activities obtained for this purpose shall be acquired from a provider accredited by ACPE, or in the alternative, by JA; and further, the credit earned for such programs may be included within the total number of credits required to renew the pharmacist license.

- 5. The pharmacist shall retain evidence of their education, training and continuing competency; and further, shall furnish copies of such documentation upon request by the board.
- 6. Sanctions
  - a. The failure of a pharmacist to obtain and maintain the education, training and continuing competency described in this Section prior to administering medications to patients or supervising other pharmacy personnel shall substantiate a violations of <u>R.S. 37:1241(A)(3)</u>, and shall subject the pharmacist to disciplinary action by the board.
  - b. The failure of a pharmacist to provide documentation of their education, training and continuing competency to administer medications when requested by the board shall substantiate a violation of R.S. 37:1241(A)(22), and shall subject the pharmacist to disciplinary action by the board.
- C. Reporting Administration of Immunizations
  - 1. The immunizing pharmacist or his designee shall report the immunization to the state immunization registry within 72 hours of the administration of the immunization. The report of an immunization administration to the state immunization registry shall satisfy any requirement for notification of such information to the patient's primary care provider.
- D. Pharmacists administering medications in a location other than a pharmacy shall comply with the following minimum standards:
  - There shall be sufficient staffing available for the pharmacist to administer the medication, supervise any
    other pharmacy personnel administering medications, and monitor the patient afterward without
    distraction from other responsibilities.
  - To facilitate emergency management of anaphylactic reactions, there shall be adequate supplies of
    medication and equipment, as well as pre-determined procedures for the arrangement of emergency
    medical services.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2085 (October 2003), effective January 1, 2004, LR 34:1409 (July 2008), amended by the Department of Health, Board of Pharmacy, LR 46:578 (April 2020), LR 47:1641 (November 2021), LR 48:494 (March 2022).

# §523. Collaborative Drug Therapy Management

A. Definitions. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:

Board - the Louisiana Board of Pharmacy.

Collaborative Drug Therapy Management or Drug Therapy Management – that practice in which a pharmacist voluntarily agrees with a physician to manage the disease specific drug therapy of one or more patients of such physician, within a predetermined range of medication selected by the physician and set forth in a patient specific written order set. Drug therapy management shall be limited to:

- a. monitoring and modifying a disease specific drug therapy;
- b. collecting and reviewing patient history;
- c. obtaining and reviewing vital signs, including pulse, temperature, blood pressure, and respiration;
- d. ordering, evaluating, and applying the results of laboratory tests directly related to the disease specific drug therapy being managed under an order set, provided such tests do not require the pharmacist to interpret such testing or formulate a diagnosis; and
- e. providing disease or condition specific patient education and counseling.

Controlled Substance – any substance defined, enumerated, or included in federal or state statute or regulations, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such statute or regulations.

Disease Specific Drug Therapy – a specific drug or drugs prescribed by a physician for a specific patient of such physician that is generally accepted within the standard of care for treatment of the disease or condition.

Drug –

- (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 diseases 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.

*Drugs of Concern* – a drug that is not a controlled substance but which is nevertheless defined and identified in accordance with procedures established by the Louisiana Prescription Monitoring Program Act, <u>R.S. 40:1001 - 1014</u>, as a drug with the potential for abuse.

*Pharmacist* – for purposes of this Section, an individual who has a current unrestricted license to practice pharmacy in this state duly licensed by the board, who is approved by the board to engage in collaborative practice for a specific disease or condition based on the *pharmacist's* training and experience.

*Physician* – an individual lawfully entitled to engage in the practice of medicine in this state as evidenced by a current, unrestricted license duly issued by the Louisiana State Board of Medical Examiners.

*Prescribe* – a request or order transmitted in writing, orally, electronically or by other means of telecommunication for a drug that is issued in good faith, in the usual course of professional practice and for a legitimate medical purpose, by a physician for the purpose of correcting a physical, mental or bodily ailment of his patient. *Order Set* – a written set of directives or instructions containing each of the components specified elsewhere in this Section for collaborative drug therapy management of disease specific drug therapy for a specific patient. The *order set* shall be signed by the physician and represents the physician orders for the collaborative drug therapy

## B. Registration

1. Eligibility

management to be provided to the patient.

- n. No pharmacist shall engage in collaborative drug therapy management in this state until registered with the board in accordance with this Section. To be eligible for registration, a pharmacist shall, as of the date of the application:
  - i. possess a current, unrestricted license to practice pharmacy issued by the board and not be the subject of a pending investigation or complaint by the board or by the pharmacy licensing authority of any other state or jurisdiction;
  - ii. be actively engaged in the practice of pharmacy in this state and the provision of pharmacist care similar to the activities anticipated in the collaborative drug therapy management agreement.
- b. A pharmacist shall be deemed ineligible for registration of collaborative drug therapy management who:
  - i. does not possess the qualifications prescribed by §523.B.1.a;
  - ii. has voluntarily surrendered or had suspended, revoked, or restricted his controlled dangerous substances license, permit, or registration (state or federal);
  - iii. has had a pharmacy license suspended, revoked, placed on probation or restricted in any manner by the board or by the pharmacy licensing authority of any other state or jurisdiction;
  - iv. has had an application for pharmacist licensure rejected or denied; or
  - v. has been, or is currently in the process of being denied, terminated, suspended, refused, limited, placed on probation or under other disciplinary action with respect to participation in any private, state, or federal health insurance program.
- c. The board may, in its discretion, waive the limitations referenced in Subparagraph B.1.b of this Section on a case-by-case basis.
- d. The board may deny registration to an otherwise eligible pharmacist for any of the causes enumerated in causes enumerated in R.S. 37:1241(A), or any other violation of the provisions of the Pharmacy Practice Act or the board's rules.
- e. The burden of satisfying the board as to the eligibility of a pharmacist for registration to engage in collaborative drug therapy management shall be upon the pharmacist. A pharmacist shall not be deemed to possess such qualifications unless and until the pharmacist demonstrates and evidences such qualifications in the manner prescribed by and to the satisfaction of the board.

# 2. Application and Issuance

- Application for registration to engage in collaborative drug therapy management shall be made upon forms supplied by the board. Application forms and instructions may be obtained from the board's website or by contacting the board's office.
- b. An application for registration to engage in collaborative drug therapy management shall include:
  - i. the pharmacist's full name, license number, mailing address of record, and emergency contact information;
  - ii. the nature of the collaborative drug therapy management activities contemplated, i.e., the disease or condition proposed for management;
  - iii. a description of the pharmacist's professional education that qualifies him to engage in collaborative drug therapy management activities described in the application;
  - iv. proof documented in a form satisfactory to the board that the pharmacist possesses the qualifications set forth in this Section; and

- v. such other information and documentation as the board may require to evidence qualification for registration.
- c. The board may reject or refuse to consider any application for registration which is not complete in every detail required by the board. The board may, in its discretion, require a more detailed or complete response to any request for information set forth in the application as a condition to consideration.
- d. A pharmacist seeking registration to engage in collaborative drug therapy management shall be required to appear before the board or its designee if the board has questions concerning the nature or scope of the pharmacist's application, finds discrepancies in the application, or for other good cause as determined by the board.
- e. When all the qualifications, requirements, and procedures of this Section are met to the satisfaction of the board, the board shall approve and register a pharmacist to engage in collaborative drug therapy management. Registration of authority to engage in collaborative drug therapy management shall not be effective until the pharmacist receives notification of approval from the board.
- f. Although a pharmacist shall notify the board each time he intends to engage in collaborative drug therapy management with a physician other than the physician identified in the pharmacist's original application, registration with the board is only required once. The board shall maintain a list of pharmacists who are registered to engage in collaborative drug therapy management.
- g. Each pharmacist registered to engage in collaborative drug therapy management shall be responsible for updating the board within 10 days in the event of any change in the information recorded in the original application.
- 3. Expiration of Registration; Renewal
  - a. A pharmacist's registration to engage in collaborative drug therapy management with a physician shall terminate and become void, null and without effect upon the earlier of:
    - i. death of either the pharmacist or physician;
    - ii. loss of license of the pharmacist;
    - iii. disciplinary action limiting the ability of the pharmacist to enter into collaborative drug therapy management;
    - iv. notification to the board that the pharmacist has withdrawn from collaborative drug therapy management;
    - v. a finding by the board of any of the causes that would render a pharmacist ineligible for registration; or
    - vi. expiration of a pharmacist's license or registration to engage in collaborative drug therapy management for failure to timely renew such license or registration.
  - b. Registration of authority to engage in collaborative drug therapy management shall expire annually on the same day as a pharmacist's license unless renewed by the pharmacist by completing the application form supplied by the board. An application for registration renewal shall be made part of and/or accompany a pharmacist's renewal application for pharmacist licensure.
  - c. The timely submission of an application for renewal of registration shall operate to continue the expiring registration in effect pending renewal of registration or other final action by the board on such application for renewal.
- C. Advisory Committee. The Collaborative Drug Therapy Management Advisory Committee, constituted as provided for in LAC 46:XLV.7417, shall assist the Board of Medical Examiners and the Board of Pharmacy on matters relative to collaborative drug therapy management. The president of the Board of Pharmacy shall appoint a pharmacist to serve on the committee, and said pharmacist shall serve at the pleasure of the Board of Pharmacy.
- D. Standards of Practice
  - 1. Authority, Responsibility, and Limitations of Collaborative Drug Therapy Management
    - a. A pharmacist registered with the board under this Section may engage in collaborative drug therapy management with a physician in accordance with a patient specific, drug specific, disease specific order set satisfying the requirements of this Section.
    - b. A pharmacist engaged in collaborative drug therapy management shall:
      - i. retain professional responsibility to his patient for the management of their drug therapy;
      - ii. establish and maintain a pharmacist-patient relationship with each patient subject to collaborative drug therapy management;
      - iii. be geographically located to be physically present to provide pharmacist care to a patient subject to collaborative drug therapy management;
      - iv. provide on a scheduled basis no less than every three months, a status report on the patient, including but not limited to, any problem, complication, or other issues relating to patient non-

- compliance with drug therapy management. This requirement may be met by entering the information in the patient's medical record; and
- v. be available through direct telecommunication for consultation, assistance, and direction.
- c. A pharmacist's registration to engage in collaborative drug therapy management with a physician is personal to the pharmacist. A pharmacist registered to engage in drug therapy management shall not allow another pharmacist not so registered or any other individual to exercise the authority conferred by such registration.
- d. Collaborative drug therapy management shall only be utilized for disease specific drug therapy as defined in this Section.
- e. The scope of the collaborative drug therapy management shall not include:
  - i. any patient of the physician for whom such physician has not prepared a patient specific, drug specific, disease or condition specific order set based on a face-to-face visit with the patient;
  - ii. initiation or discontinuance of drug therapy by a pharmacist, except as specified in the order set:
  - iii. the management of controlled substances or drugs of concern; or
  - iv. substitution of a drug prescribed by a physician without the explicit written consent of such physician.

#### 2. Informed Consent

- a. A pharmacist shall not engage in collaborative drug therapy management of a patient without the patient's written informed consent.
- b. In addition to the requirements provided by law for obtaining a patient's informed consent, each patient who is subject to collaborative drug therapy management shall be:
  - i. informed of the collaborative nature of drug therapy management for the patient's specific medical disease or condition and provided instructions and contact information for follow-up visits with the pharmacist and physician;
  - ii. informed he may decline to participate in a collaborative drug therapy management practice and may withdraw at any time without terminating the physician-patient or pharmacist-patient relationship; and
  - iii. provided written disclosure of any contractual or financial arrangement with any other party that may impact one of the party's decision to participate in the agreement.
- All services provided shall be performed in a setting which insures patient privacy and confidentiality.

#### 3. Order Sets

- a. A separate order set shall be written for each patient to be managed by collaborative drug therapy management. A copy of each order set shall be:
  - i. provided to the collaborating physician and pharmacist; and
  - ii. made part of the patient's pharmacy record.
- b. A physician shall develop a patient specific order set for a particular patient or utilize a standard written protocol order set, incorporating what patient specific deviations, if any, the physician may deem necessary or appropriate for such patient. In either event, an order set for disease specific drug therapy shall adhere to generally accepted standards of care and shall identify, at a minimum:
  - i. the pharmacist, the physician, and telephone number and other contact information for each;
  - ii. the patient's name, address, gender, date of birth, and telephone number;
  - iii. the disease or condition to be managed;
  - iv. the disease specific drug or drugs to be utilized;
  - v. the type and extent of drug therapy management the physician authorizes the pharmacist to perform;
  - vi. the specific responsibilities of the pharmacist and physician;
  - vii. the procedures, criteria, or plan the pharmacist is required to follow in connection with drug therapy management;
  - viii. the specific laboratory test or tests, if any, directly related to drug therapy management the physician authorizes the pharmacist to order and evaluate;
  - ix. the reporting and documentation requirements of the pharmacist and physician respecting the patient and schedule by which such are to take place;
  - x. the conditions and events upon which the pharmacist and physician are required to notify one another; and
  - xi. procedures to accommodate immediate consultation by telephone or direct telecommunication with, between, or among the pharmacist, physician, and the patient.

- c. Each order set utilized for collaborative drug therapy management of a patient shall be reviewed annually by the collaborating physician, or more frequently as such physician deems necessary, to address patient needs and to insure compliance with the requirements of this Section. The physician's signature and date of review shall be noted on the order set and maintained by the pharmacist in accordance with this Section.
- 4. Reporting Obligations and Responsibilities
  - a. A pharmacist engaged in collaborative drug therapy management shall report annually, as a condition to the renewal of his registration, whether or not and the extent to which the pharmacist is engaged in collaborative drug therapy management and such other information as the board may request.
  - b. A pharmacist engaged in collaborative drug therapy management shall comply with reasonable requests by the board for personal appearances or information relative to the functions, activities, and performance of a pharmacist or physician engaged in collaborative drug therapy management.

#### 5. Records

- a. The following information shall be included in the pharmacy's record of a patient subject to collaborative drug therapy management:
  - i. the prescription or order implementing collaborative drug therapy management;
  - ii. the order set applicable to the patient evidencing documentation of the physician's annual review;
  - iii. documentation of all activities performed by the pharmacist;
  - iv. consultations and status reports by and between the pharmacist and physician; and
  - v. documentation of the patient's informed consent to collaborative drug therapy management.
- b. A pharmacist registered to engage in collaborative drug therapy management shall maintain and produce, upon inspection conducted by or at the request of a representative of the board, a copy of any order sets and such other records or documentation as may be requested by the board to assess a pharmacist's compliance with requirements of this Section, the Pharmacy Practice Act, or other applicable board rules.

#### E. Sanctions

- 1. Action Against Registration. For noncompliance with any of the provisions of this Section, the board may, in addition to or in lieu of administrative proceedings against a pharmacist's license, suspend or revoke a pharmacist's registration to engage in collaborative drug therapy management, or may impose such terms, conditions, or restrictions thereon as the board may deem necessary or appropriate.
- 2. Action Against Pharmacist License. Any violation or failure to comply with the provisions of this Section shall be deemed a violation of R.S. 37:1241(A)(1), as well as a violation of any other applicable provisions of R.S. 37:1241(A), providing cause for the board to take any of the actions permitted in R.S. 37:1241(A) against the pharmacist's license.
- 3. Unauthorized Practice. Nothing in this Section shall be construed as authorizing a pharmacist to issue prescriptions, exercise independent medical judgment, render diagnoses, provide treatment, assume independent responsibility for patient care, or otherwise engage in the practice of medicine as defined in the <a href="Louisiana Medical Practice Act">Louisiana Medical Practice Act</a>. Any person who engages in such activities, in the absence of medical licensure issued by the Louisiana State Board of Medical Examiners, shall be engaged in the unauthorized practice of medicine and subject to the penalties prescribed by the Louisiana Medical Practice Act.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1164(37)(b)(i). HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1125 (June 2007), amended LR 39:3291 (December 2013).

# §525. Cognitive Services

A. Definitions. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section.

Cognitive Services – those acts and operations related to a patient's drug therapy that are judgmental in nature, based on knowledge, and derived from empirical factual information. Such services may include, but are not necessarily limited to, the following:

- a. drug regimen review, drug use evaluation and drug information;
- b. provision of advice and counsel on drugs, the selection and use thereof to the facility, the patients therein, the healthcare providers of the facility regarding the appropriateness, use, storage, handling, administration and disposal of drugs within the facility;
- c. participation in the development of policies and procedures for drug therapy within the institution, including storage, handling, administration and disposing of drugs and devices;

- d. assuring the compliance with all applicable laws, rules and regulations;
- e. provision of educational and drug information sources for the education and training of the facility healthcare professionals;
- f. accepting responsibility for the implementation and performance of review of quality-related or sentinel events.

#### B. Practice.

- 1. A pharmacist who provides cognitive services to Louisiana residents shall be licensed by the board.
- 2. Cognitive services provided from outside a permitted pharmacy may not include the physical dispensing of medications to patients.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182. HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1234 (May 2012).

#### [End of Chapter 5]

#### *Note:*

<sup>&</sup>lt;sup>1</sup> The statutory list of fees in R.S. 37:1184 is no longer current. The current list of fees is found in Chapter 1 of the administrative code, more specifically in Section 115. The board has not yet revised Section 505 to remove the obsolete citation.

# **Chapter 7. Pharmacy Interns**

# §701. Definition

- A. A pharmacy intern is an individual who is not yet licensed as a pharmacist in any jurisdiction, and is:
  - 1. 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; or
  - 2. a graduate of a board-approved college of pharmacy awaiting examination for licensure; or
  - 3. a graduate who has established educational equivalency through a program approved by the board; or
  - 4. an individual participating in a residency or fellowship.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1306 (October 1997), LR 26:2284 (October 2000), LR 29:2086 (October 2003), effective January 1, 2004.

# §703. Registration

- A. All pharmacy interns shall meet the following requirements for registration:
  - 1. All pharmacy interns shall register with the board. The failure to register may result in disciplinary action by the board.
    - a. The applicant shall submit to the board office a properly completed application no later than the end of the first semester of the first academic year at a board-approved college of pharmacy.
    - b. The board may issue an intern registration to the applicant, upon receipt of a properly completed application, appropriate fee, and any other documentation required by the board office.
    - c. The intern registration shall expire one year after the certification of graduation from a board-approved college of pharmacy.
      - Intern registrations issued to foreign pharmacy graduates shall expire two years after the date of issue
    - d. The board shall reserve the right to recall or refuse to issue any intern registration for cause.
  - 2. A pharmacy intern shall wear appropriate attire and be properly identified with his name and intern status while on duty at the preceptor site.
  - 3. A pharmacy intern shall notify the board in writing within 10 days of a change of address. This notice shall include the pharmacy intern's name, registration number, and old and new addresses.
  - 4. A pharmacy intern shall notify the board in writing within 10 days of a change in location(s) of employment. This notice shall include the pharmacy intern's name and registration number, the name and address of old and new employment, and the permit number of those pharmacies involved.
  - 5. The pharmacy intern shall be non-impaired.
    - a. The pharmacy intern is subject to confidential random drug screen testing and/or evaluations.
    - b. A positive drug screen may be self-evident as proof of improper drug use. For the purposes of this Chapter, a missed screen, a screen submitted beyond the mandated period, and/or any screen submitted indicating the sample provided is diluted, substituted, or in any way adulterated is considered to be a positive drug screen.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 26:2285 (October 2000), LR 29:2086 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 43:2163 (November 2017), effective January 1, 2018.

# §705. Professional Experience

- A. All applicants for licensure by examination shall earn professional experience in the practice of pharmacy concurrent with attending or after graduation from a board-approved college of pharmacy.
- B. The practical experience shall be predominantly related to the provision of pharmacy primary care and the dispensing of drugs and medical supplies, the compounding of prescriptions, and the keeping of records and making of reports as required under federal and state law.
  - 1. The practical experience earned shall have been under the supervision of a pharmacist, or in the alternative, a licensed practitioner.
  - 2. A pharmacy intern shall not practice in a permitted pharmacy site that is on probation with the board. A pharmacy interns shall not practice under the supervision of a pharmacist or other licensed practitioner whose license is on probation with their primary professional licensing agency.

- C. Professional Experience Hours. To qualify for pharmacist licensure, an intern shall supply evidence of the acquisition of at least 1,740 hours of professional experience, of which at least 1,500 hours of which shall be practical experience as described in Subsection B above.
  - 1. The board shall award 1,740 hours credit to an intern for his successful completion of a professional experience curriculum at a board-approved college of pharmacy. The dean of the board-approved college of pharmacy shall certify the completion of this requirement in the manner prescribed by the board office.
  - 2. In the event an applicant for pharmacist licensure by examination is unable to document the acquisition of 1,740 hours of professional experience through the successful completion of a professional experience curriculum at a board-approved college of pharmacy by means of an attestation from the dean of that college, then the applicant shall demonstrate the acquisition of at least 1,740 hours of pre-licensure practical experience in a licensed pharmacy, subject to the following limitations:
    - a. The pharmacy permit shall not have been on probation or otherwise restricted during the time the hours were earned.
    - b. The license of the pharmacist supervising the intern and signing the affidavit shall have been issued no less than two years before supervising the intern, and further, shall not have been on probation or otherwise restricted during the time the hours were earned.
  - 3. Practical experience hours that are submitted to the board for credit consideration (other than those attested to by the dean of the college of pharmacy for the successful completion of a professional experience curriculum at a board-approved college of pharmacy) shall be listed on an affidavit form supplied by the board office, and signed by the supervising pharmacist and pharmacy intern.
    - a. A pharmacy intern may receive credit for a maximum of 50 hours per week.
    - b. A separate affidavit shall be required from each permitted pharmacy site.
    - c. No credit shall be awarded for hours earned within the professional experience curriculum of a board-approved college of pharmacy, nor for hours earned outside the professional experience curriculum but at the same time and location as hours earned for that professional experience curriculum.
  - 4. Certification of Hours to and from another Jurisdiction.
    - a. Interns enrolled in a board-approved college of pharmacy in Louisiana who earn hours of professional experience in another jurisdiction, as well as interns enrolled in a board-approved college of pharmacy in another jurisdiction who earn hours of professional experience in another jurisdiction, may transfer those hours to Louisiana under the following conditions:
      - i. The hours of practical experience shall be listed on an affidavit form supplied by the Louisiana Board of Pharmacy, signed by the supervising pharmacist and the intern, and submitted to the Louisiana Board of Pharmacy for consideration of credit; and
      - ii. The board of pharmacy in the jurisdiction where the hours were earned shall certify those hours to the Louisiana Board of Pharmacy.
      - iii. The Louisiana Board of Pharmacy may grant credit for all hours that comply with the Louisiana Board of Pharmacy's requirements as delineated in this Section.
    - b. Upon written request by the pharmacy intern, the Louisiana Board of Pharmacy may certify professional experience hours earned in Louisiana to a board of pharmacy in another jurisdiction.
  - 5. Credited hours of practical experience shall expire two years after the expiration date of the intern registration and shall no longer be valid for licensure purposes.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 26:2285 (October 2000), LR 29:2086 (October 2003), effective January 1, 2004, LR 32:636 (April 2006), LR 32:2256 (December 2006), LR 33:1130 (June 2007), LR 34:1409 (July 2008), amended by the Department of Health, Board of Pharmacy, LR 43:2163 (November 2017), effective January 1, 2018.

# §707. Impairment

- A. *Impairment* or *Impaired* a condition that causes an infringement on the ability of a person to practice, or assist in the practice, of pharmacy sufficient to pose a danger to the public. *Impairment* may be caused by, but is not limited to, alcoholism, substance abuse or addiction, mental illness, or physical illness.
- B. Pharmacy interns shall be non-impaired.
- C. Pharmacy interns who have knowledge a pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician candidate is impaired shall notify the board of that fact as soon as possible.
- D. Pharmacy interns may be subject to a medical evaluation for impairment by a board approved addictionist, as authorized by the Louisiana Pharmacy Practice Act, <u>R.S. 37:1161</u> et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1130 (June 2007).

## §709. Scope of Practice

- A. Pharmacy interns may perform any duty of a pharmacist provided he is under the supervision of a pharmacist.
- B. The ratio of pharmacy interns, certified pharmacy technicians, and pharmacy technician candidates to pharmacists on duty shall not exceed four to one in any variable at any given time, of which the ratio of pharmacy technician candidates to pharmacists shall be no more than two to one. In addition, the ratio of pharmacy interns on rotation with a board approved college of pharmacy to pharmacists shall be no more than three to one.
- C. A pharmacy intern may not:
  - 1. present or identify himself as a pharmacist;
  - 2. sign or initial any document which is required to be signed or initialed by a pharmacist unless a preceptor cosigns the document; or
  - 3. independently supervise pharmacy technicians or pharmacy technician candidates.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 36:755 (April 2010), amended by the Department of Health, Board of Pharmacy, LR 48:495 (March 2022), amended LR 49:1558 (September 2023).

# §711. Administration of Medications

- A. Education and Training Required; Supervision
  - 1. Pharmacy interns who intend to administer medications to their patients shall obtain the education and training described within this Section prior to engaging in such activity.
  - 2. Pharmacy interns, once properly qualified as required by the provisions of this Section, may only administer medications to patients while under the supervision of a pharmacist with the same qualification in medication administration as described in Chapter 5 of this Part.
- B. Education, Training and Continuing Competency
  - 1. A pharmacy intern who intends to administer medications to patients shall possess a pharmacy intern registration in active status. In the event the registration is lapsed, suspended, or in any other inactive status, the pharmacy intern shall not administer medications. A pharmacy intern with a registration in restricted status may administer medications unless the restriction imposed by the board prevents such activity.
  - 2. The pharmacy intern shall successfully complete a certificate program for medication administration which is an evidence-based didactic course that meets current Centers for Disease Control and Prevention (CDC) training guidelines. The certificate program shall be acquired from a provider accredited by ACPE, or in the alternative, by Joint Accreditation (JA), and further, the certificate program shall provide a minimum of 20 hours of instruction and experiential training in the following content areas:
    - a. standards for medication administration practices;
    - b. basic immunology;
    - c. recommended medication administration schedules;
    - d. vaccine storage and management;
    - e. informed consent;
    - f. physiology and techniques for medication administration;
    - g. pre- and post-administration assessment and counseling;
    - h. medication administration record management; and
    - i. management of adverse events, including identification and appropriate response, as well as documentation and reporting.
  - 3. The pharmacy intern shall complete a life safety certification by the American Heart Association through its Basic Life Support (BLS) CPR and AED Training for Healthcare Professionals course, or its successor, or through an equivalent course sponsored by an alternative vendor. The pharmacy intern may substitute the Advanced Cardiac Life Support (ACLS) course for the BLS standard; however, the Heartsaver CPR and AED or other courses intended for the general public shall not be sufficient to meet this standard. The pharmacy intern shall renew their certification prior to the expiration date assigned by the course provider.
  - 4. To maintain continuing competency for medication administration, the pharmacy intern shall acquire at least one hour of continuing pharmacy education per year related to this topic. Continuing pharmacy education activities obtained for this purpose shall be acquired from a provider accredited by ACPE, or in the alternative, by JA.

- 5. The pharmacy intern shall retain evidence of their education, training and continuing competency; and further, shall furnish copies of such documentation upon request by the board.
- 6. Sanctions
  - a. The failure of a pharmacy intern to obtain and maintain the education, training and continuing competency described in this Section prior to administering medications to patients shall substantiate a violations of R.S. 37:1241(A)(3), and shall subject the pharmacy intern to disciplinary action by the board.
  - b. The failure of a pharmacy intern to provide documentation of their education, training and continuing competency to administer medications when requested by the board shall substantiate a violation of R.S. 37:1241(A)(22), and shall subject the pharmacy intern to disciplinary action by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182. HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 48:495 (March 2022).

[End of Chapter 7]

# **Chapter 9. Pharmacy Technicians**

# §901. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section: *ACPE* – Accreditation Council for Pharmacy Education.

*CPE* – continuing pharmaceutical education, as part of a postgraduate educational program to enhance professional competence.

<u>CPE Monitor</u> – a collaborative service from the National Association of Boards of Pharmacy (NABP) and the Accreditation Council for Pharmacy Education (ACPE) that provides an electronic system for pharmacists and pharmacy technicians to record and track their completed CPE activities.

*CPE unit* – a standard of measurement adopted by the ACPE for the purpose of accreditation of CPE programs. One CPE unit is equivalent to 10 credit hours.

*Pharmacy Technician* – an individual, certified by the board, who assists in the practice of pharmacy under the direct and immediate supervision of a Louisiana-licensed pharmacist.

*Pharmacy Technician Candidate* – an individual, registered by the board, training to become a pharmacy technician, who assists in the practice of pharmacy under the direct and immediate supervision of a Louisiana-licensed pharmacist.

*Training Program* – a pharmacy technician training program that is currently nationally-accredited and has been approved by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2485 (November 2004), effective January 1, 2005, amended LR 39:1777 (July 2013), amended by the Department of Health, Board of Pharmacy, LR 43:2496 (December 2017), effective January 1, 2018.

# §903. Pharmacy Technician Candidates

#### A. Registration

1. All pharmacy technician candidates shall obtain a registration from the board prior to performing any professional functions in a pharmacy; failure to do so may result in disciplinary action by the board.

#### 2. Qualifications

- a. The applicant shall be at least 18 years of age, as evidenced by a valid and legible copy of a birth certificate or other appropriate credential.
- b. The applicant shall be of good moral character and non-impaired.
- c. The applicant shall satisfy one of the following eligibility criteria:
  - i. proof of enrollment in a nationally-accredited and board-approved pharmacy technician training program; or
  - ii. proof of successful completion of a board-approved technician certification examination, and further, proof of successful completion of a high school approved by a state department of education or an equivalent degree of education, as evidenced by a valid and legible copy of a diploma, transcript, or other appropriate credential

#### d. Exceptions:

- i. A pharmacist or pharmacy intern whose board credential has been denied, suspended, revoked, or restricted for disciplinary reasons by any board of pharmacy shall not be a pharmacy technician candidate or pharmacy technician.
- ii. A pharmacist or pharmacy intern whose board credential is lapsed shall not be a pharmacy technician candidate or pharmacy technician until such lapsed credential is recalled through non-disciplinary board action.

#### 3. Issuance and Maintenance

- a. Upon receipt of a properly completed application, appropriate fee, and any other documentation required by the board, the board may issue a Pharmacy Technician Candidate Registration to the applicant.
- b. The board reserves the right to refuse to issue, recall, or discipline a registration for cause.
- c. The registration shall expire 24 months after the date of issuance, and it shall not be renewable.
- d. Termination of Enrollment; Status of Registration
  - i. In the event the candidate is no longer enrolled in a nationally-accredited and board-approved pharmacy technician training program for any reason other than graduation, the candidate no longer meets the eligibility criteria to possess the registration, and the candidate shall relinquish the registration to the board, giving notice of their last day of enrollment in the program.

- ii. In the event a candidate fails to relinquish their registration when required to do so, or when notified by the board office of that requirement, the board staff shall inactivate the registration and refer the matter to the board for its consideration of disciplinary action against the candidate.
- iii. In the event the candidate should re-enroll in the original program or a different program, and gives proof of that enrollment to the board, the board may re-issue the registration with the original expiration date preserved.
- iv. In its discretion, the board may grant an exception to the original expiration date upon request by the candidate demonstrating unusual circumstances.
- e. A pharmacy technician candidate shall notify the board, in writing, no later than 10 days following a change of mailing address. The written notice shall include the candidate's name, registration number, and old and new addresses.
- f. A pharmacy technician candidate shall notify the board, in writing, no later than 10 days following a change in location(s) of employment. The written notice shall include the candidate's name, registration number, and name, address, and permit numbers for old and new employers.

#### B. Training Programs

- 1. All training programs approved by the board shall maintain their national accreditation.
- 2. The training program shall notify the board when a pharmacy technician candidate is no longer enrolled in the program. Evidence of a program's failure to comply with this rule shall constitute sufficient basis for the withdrawal of the board's approval for the program.
- 3. The training program shall provide an appropriate credential to the pharmacy technician candidate who has successfully completed the program, provided, however, that such credential shall not be formatted in such a manner to lead anyone to believe that credential resembles a document providing legal authority to practice as a pharmacy technician.

#### C. Practical Experience

- 1. The candidate shall possess a registration prior to performing any permitted professional function or earning any practical experience in a pharmacy.
- 2. The candidate shall wear appropriate attire and be properly identified as to name and candidate status while on duty in the prescription department.
- 3. A candidate shall not work in a permitted site that is on probation with the board, or with a pharmacist who is on probation with the board.
- 4. The candidate's registration shall evidence his authority to earn practical experience in a pharmacy, under the supervision of a pharmacist, in satisfaction of the requirements for pharmacy technician certification.
  - a. in the event the registration was issued to an applicant enrolled in a nationally-accredited and board-approved training program, the candidate shall earn the amount of experience prescribed by the curriculum of that program, which may include hours earned in a consultant pharmacy practice which does not hold a pharmacy permit; or
  - b. in the event the registration was issued to an applicant by any other method, the candidate shall earn at least 600 hours of practical experience in a pharmacy in Louisiana, provided however, that a candidate may receive board credit for a maximum of 50 hours per week.
- 5. Hours of practical experience earned by a candidate shall expire two years after the expiration date of the registration.

#### D. Examination

- 1. A board-approved technician examination shall consist of integrated pharmacy subject matter and any other disciplines the board may deem appropriate in order to permit the candidate to demonstrate his competency. The candidate shall achieve a passing score, as determined by the board.
- 2. In the event the candidate fails the examination, the candidate may repeat the examination in compliance with the test administrator's policy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2485 (November 2004), effective January 1, 2005, amended LR 39:1777 (July 2013), amended by the Department of Health, Board of Pharmacy, LR 43:2496 (December 2017), effective January 1, 2018, repromulgated LR 44:49 (January 2018), amended LR 46:574 (April 2020), amended LR 46:576 (April 2020).

# §904. Preferential Licensing Procedures for Military-Trained Applicants and Their Dependents

A. Definitions. The following terms shall have the meaning ascribed to them in this Subsection:

*Dependent* – a resident spouse or resident unmarried child under the age of 21 years, a child who is a student under the age of 24 years and who is financially dependent upon the parent, or a child of any age who is disabled and dependent upon the parent.

Jurisdiction – any state or territory of the United States of America.

*Military* – the armed forces or reserves of the United States, including the Army, Navy, Marine Corps, Coast Guard, Air Force, and the reserve components thereof, the National Guard of any state, the Military Reserves of any state, or the naval militia of any state.

- B. Eligibility. The following persons are eligible for the preferential licensing procedures provided by this Section:
  - 1. a member of the military who has been assigned to duty in Louisiana or his dependent;
  - 2. a civilian employee of the United States Department of Defense who has been assigned to duty in Louisiana or his dependent;
  - 3. a member of the military or civilian employee of the United States Department of Defense or their dependents who have established this state as their state of legal residence in their military record.
- C. Requirements. Eligible persons seeking preferential licensing procedures shall demonstrate compliance with the following requirements:
  - 1. The applicant holds a current and valid pharmacy technician credential issued by the pharmacy regulatory authority in another jurisdiction.
  - 2. The applicant has held the license in the other jurisdiction for at least one year.
  - 3. The applicant has satisfied all educational and experiential requirements required by the pharmacy regulatory authority in the other jurisdiction.
  - 4. The applicant is held in good standing by the pharmacy regulatory authority in the other jurisdiction, or in the event such status is not used in this jurisdiction, the applicant holds an unrestricted license in that jurisdiction.
  - 5. The applicant does not have a disqualifying criminal record as determined by the board.
  - 6. The applicant has not had an occupational license revoked by a board in another jurisdiction due to negligence or intentional misconduct related to the applicant's work in the occupation in another jurisdiction.
  - 7. The applicant has not surrendered an occupational licensed due to negligence or intentional misconduct related to the applicant's work in the occupation in another jurisdiction.
  - 8. The applicant does not have a complaint, allegation, or investigation pending before a pharmacy regulatory authority in another jurisdiction which relates to unprofessional conduct or an alleged crime. If the applicant has a complaint, allegation, or investigation pending, the board shall not issue or deny a pharmacy technician certificate until the complaint, allegation, or investigation is resolved, or the applicant otherwise satisfies the criteria for a pharmacy technician certificate in this state to the satisfaction of the board.
  - 9. The applicant has paid all applicable fees in this state.
  - 10. The applicant has applied for a permanent pharmacy technician certificate in this state. In the event the applicant fails to qualify for a permanent pharmacy technician certificate as determined by the board, the special work permit issued under the authority of Subsection E of this Section shall be automatically terminated.
- D. Upon receipt of an application for a pharmacy technician certificate by an eligible applicant, the board staff shall mark the application for priority processing and preserve that status until the pharmacy technician certificate is issued, or in the alternative, the board gives notice of its intent to deny the application and refuse to issue the certificate. The board shall notify the applicant of its licensing decision within 30 calendar days after receiving an application.
- E. In the event the applicant intends to assist in the practice of pharmacy before the issuance of the permanent pharmacy technician certificate, the board may issue a special work permit to the applicant.
  - 1. The special work permit shall expire 120 days after the date of issue and the permit shall not be renewable.
  - 2. The special work permit shall identify the applicant, and further, shall indicate the authority for that person to assist in the practice of pharmacy within the state of Louisiana as well as the dates of issue and expiration of the credential.
  - 3. No applicant may assist in the practice of pharmacy prior to the issuance of a special work permit or pharmacy technician certificate, or with an expired special work permit or pharmacy technician certificate.

- 4. The special work permit shall not be eligible for license transfer or reciprocity to any other jurisdiction.
- 5. The provisions of this Section shall not apply to a member of the military who has received, or is in the process of receiving, a dishonorable discharge from the military. Further, the provisions of this Section shall not apply to the spouse of a member of the military who has received, or is in the process of receiving, a dishonorable discharge from the military.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:3075 (November 2013), amended by the Department of Health, Board of Pharmacy, LR 47:245 (February 2021).

# §905. Pharmacy Technician Certificate

#### A. Qualifications

- 1. An applicant for a pharmacy technician certificate shall be at least 18 years of age, as evidenced by a valid and legible copy of a birth certificate or other appropriate credential.
- 2. An applicant shall be of good moral character and non-impaired.
- 3. An applicant shall demonstrate one of the following educational competences:
  - a. In the event the applicant obtained their technician candidate registration on the basis of their enrollment in a nationally-accredited and board-approved pharmacy technician training program, the applicant shall demonstrate successful completion of that training program, or in the alternative, another nationally-accredited and board-approved pharmacy technician training program.
  - b. In the event the applicant obtained their technician candidate registration by any other method, the applicant shall demonstrate the acquisition of at least 600 hours of practical experience under the supervision of a pharmacist, using a form supplied by the board.
  - c. In the event the applicant has been licensed, registered, or otherwise credentialed by another state board of pharmacy and has been practicing for at least one year as a pharmacy technician in that state, the applicant shall demonstrate successful completion of a board-approved pharmacy technician certification examination.
- 4. An applicant shall demonstrate successful completion of a board-approved technician examination, as evidenced by a valid and legible copy of the appropriate credential.

#### B. Issuance and Maintenance

- 1. Upon receipt of a properly completed application, copies of valid and legible credentials, the appropriate fee, and any other documentation required by the board, and following verification that all requirements have been satisfied, the board may issue a pharmacy technician certificate to the applicant for the current renewal period.
- 2. The board reserves the right to refuse to issue, recall, or discipline a certificate for cause.
- 3. The annual renewal shall expire and become null and void on June 30 of each year.
  - a. The board shall make available, no later than May 1 of each year, an application for renewal to all pharmacy technicians to the address of record.
  - b. The completed application, along with the appropriate fee, shall be submitted to the board by June 30 of each year.
  - A pharmacy technician shall not assist in the practice of pharmacy in Louisiana with an expired renewal.
  - d. An application for an expired pharmacy technician renewal, along with the appropriate fee, shall be submitted to the board's reinstatement committee for consideration.
- 4. A pharmacy technician shall notify the board, in writing, no later than 10 days following a change of mailing address. The written notice shall include the technician's name, certificate number, and old and new addresses.
- 5. A pharmacy technician shall notify the board, in writing, no later than 10 days following a change in location(s) of employment. The written notice shall include the technician's name, certificate number, and name, address, and permit numbers for old and new employers.
- 6. Upon written request of any certified pharmacy technician in active military service of the United States or any of its allies, the board may waive the requirement for the annual renewal of the certificate, including

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2486 (November 2004), effective January 1, 2005, amended LR 38:1235 (May 2012), LR 39:1777 (July 2013), amended by the Department of Health, Board of Pharmacy, LR 43:2497 (December 2017), effective January 1, 2018, amended LR 46:576 (April 2020).

# §906. Preferential Licensing Procedures for Dependents of Healthcare Professionals Relocating to Louisiana

- A. Definitions.
  - 1. As used in this Section, the following terms shall have the meaning ascribed to them in this Subsection: *Dependent* any of the following who relocates to Louisiana with a healthcare professional:
    - i. the healthcare professional's spouse;
    - ii. the healthcare professional's unmarried child under the age of 21 years;
    - iii. the healthcare professional's child who is a student under the age of 24 years and who is financially dependent upon the healthcare professional;
    - iv. the healthcare professional's child of any age who is disabled and financially dependent upon the healthcare professional.

Healthcare Professional – a person who provides healthcare or professional services in Louisiana as a physician, physician assistant, dentist, registered or licensed practical nurse or certified nurse assistant, advanced practice registered nurse, certified emergency medical technician, paramedic, certified registered nurse anesthetist, nurse practitioner, respiratory therapist, clinical nurse specialist, pharmacist, physical therapist, occupational therapist, licensed radiologic technologist, chiropractor, or licensed clinical laboratory scientist; and further, has relocated to and established his legal residence in Louisiana, holds a valid license to provide healthcare services in Louisiana, and is providing healthcare services in Louisiana.

- B. Upon receipt of an application for a pharmacy technician certificate by a dependent of a healthcare professional, the board staff shall mark the application for priority processing and preserve that status until the certificate is issued, or in the alternative, the board gives notice of its intent to deny the application and refuse to issue the certificate. The board shall notify the applicant of its licensing decision within 30 calendar days after receiving a complete application.
- C. In the event the applicant intends to practice pharmacy before the issuance of the pharmacy technician certificate, the board shall issue a special work permit to the applicant.
  - 1. The special work permit shall identify the applicant and shall indicate the authority for that person to practice pharmacy within the state of Louisiana as well as the dates of issue and expiration of that permit.
  - 2. The special work permit shall expire 120 days after the date of issue and that permit shall not be renewable.
  - 3. No applicant may practice pharmacy prior to the issuance of the special work permit or pharmacy technician certificate, or with an expired special work permit or expired pharmacy technician certificate.
  - 4. The special work permit shall not be eligible for license transfer or reciprocity to any other jurisdiction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1751.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 49:67 (January 2023).

#### §907. Scope of Practice

- A. Pharmacy technician candidates and pharmacy technicians may assist the pharmacist by performing those duties and functions assigned by the pharmacist while under his direct and immediate supervision.
  - 1. The ratio of pharmacy technician candidates, certified pharmacy technicians, and pharmacy interns to pharmacists on duty shall not exceed four to one in any variable at any given time, of which the ratio of pharmacy technician candidates to pharmacists shall be no more than two to one.
- B. Pharmacy technician candidates shall not:
  - 1. receive verbal initial prescription orders;
  - 2. give or receive verbal transfers of prescription orders;
  - 3. interpret prescription orders (however, a technician candidate may translate prescription orders);
  - 4. compound high-risk sterile preparations, as defined by the United States Pharmacopeia (USP), or its successor;
  - 5. counsel patients.
  - 6. administer medications.
- C. Pharmacy technicians shall not:
  - 1. release a verbal prescription order for processing until it is reduced to written form and initialed by the receiving technician and supervising pharmacist;
  - 2. interpret prescription orders (however, a technician may translate prescription orders);
  - 3. counsel patients.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2486 (November 2004), effective January 1, 2005, amended LR 32:1049 (June 2006), amended by the Department of Health, Board of Pharmacy, LR 43:2498 (December 2017), effective January 1, 2018, amended LR 48:496 (March 2022) LR 49:1558 (September 2023).

## §909. Continuing Education

- A. A minimum of one technician-specific ACPE or board-approved CPE unit, or 10 credit hours, shall be required each year as a prerequisite for annual renewal of a pharmacy technician certificate. Such CPE units shall be credited in the 12-month period prior to the expiration date of the certificate.
- B. Certified pharmacy technicians shall maintain copies of their individual records of personal CPE activities with CPE Monitor and shall authorize the board's access to their file by recording their Louisiana pharmacy technician certificate number within that file, and shall present a copy of their CPE Monitor transcript when requested by the board.
- C. If judged appropriate by the board, some or all of the required number of hours may be mandated on specific subjects. When so deemed, the board shall notify all certified pharmacy technicians prior to the beginning of the renewal year in which the CPE is required.
- D. Complete compliance with CPE rules is a prerequisite for renewal of a pharmacy technician certificate.
  - 1. Non-compliance with the CPE requirements shall be considered a violation of <u>R.S. 37:1241(A)(2)</u> and shall constitute a basis for the board to refuse annual renewal.
  - 2. The failure to maintain an individual record of personal CPE activities, or falsifying CPE documents, shall be considered a violation of R.S. 37:1241(A)(22).
  - 3. The inability to comply with CPE requirements shall be substantiated by a written explanation, supported with extraordinary circumstances, and submitted to the board for consideration.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 30:2487 (November 2004), effective January 1, 2005, amended LR 39:1778 (July 2013), amended by the Department of Health, Board of Pharmacy, LR 43:2498 (December 2017), effective January 1, 2018.

#### §911. Impairment

- A. Pharmacy technician candidates and pharmacy technicians shall be non-impaired.
- B. Pharmacy technician candidates and pharmacy technicians who have knowledge that a pharmacist, pharmacist intern, pharmacy technician candidate, or pharmacy technician is impaired shall notify the board of that fact.
- C. Pharmacy technician candidates and pharmacy technicians shall be subject to a medical evaluation for impairment by a board-approved addictionist, as authorized by the Louisiana Pharmacy Practice Act, R.S. 37:1161 et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1212.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 17:779 (August 1991), repromulgated LR 19:1025 (August 1993), LR 23:1308 (October 1997), LR 30:2487 (November 2004), effective January 1, 2005.

#### §913. Administration of Medications

- A. Education and Training Required; Supervision
  - 1. Pharmacy technicians who intend to administer medications to their patients shall obtain the education and training described within this Section prior to engaging in such activity.
  - 2. Pharmacy technicians, once properly qualified as required by the provisions of this Section, may only administer medications to patients while under the supervision of a pharmacist with the same qualification in medication administration as described in Chapter 5 of this Part.
- B. Education, Training and Continuing Competency
  - A pharmacy technicians who intends to administer medications to patients shall possess a pharmacy
    technician certificate in active status. In the event the certificate is lapsed, suspended, or in any other
    inactive status, the pharmacy technician shall not administer medications. A pharmacy technician with a
    certificate in restricted status may administer medications unless the restriction imposed by the board
    prevents such activity.
  - 2. The pharmacy technician shall successfully complete a certificate program for medication administration which is an evidence-based didactic course that meets current Centers for Disease Control and Prevention (CDC) training guidelines. The certificate program shall be acquired from a provider accredited by ACPE, or in the alternative, by Joint Accreditation (JA); and further, the certificate program shall provide a minimum of six hours of instruction and experiential training in the following content areas:

- a. recognition of vaccines and other medications and their corresponding routes of administration;
- b. proper storage of vaccines and other medications;
- c. safety procedures to avoid accidental needlestick injuries;
- d. selection of proper needle length for injectable medications based on patient parameters;
- e. proper technique for preparation and administration of medication;
- f. demonstration of appropriate patient distraction techniques during medication administration;
- g. demonstration of appropriate technique for intramuscular and subcutaneous injections;
- h. demonstration of use of universal precautions pertinent to bloodborne pathogens;
- i. procedures for management of adverse reactions; and
- j. proper documentation procedures.
- 3. The pharmacy technician shall complete a life safety certification by the American Heart Association through its Basic Life Support (BLS) CPR and AED Training for Healthcare Professionals course, or its successor, or through an equivalent course sponsored by an alternative vendor. The pharmacy technician may substitute the Advanced Cardiac Life Support (ACLS) course for the BLS standard; however, the Heartsaver CPR and AED or other courses intended for the general public shall not be sufficient to meet this standard. The pharmacy technician shall renew their certification prior to the expiration date assigned by the course provider.
- 4. To maintain continuing competency for medication administration, the pharmacy technician shall acquire at least one hour of continuing pharmacy education per year related to this topic. Continuing pharmacy education activities obtained for this purpose shall be acquired from a provider accredited by ACPE, or in the alternative, by JA; and further, the credit earned for such programs may be included within the total number of credits required to renew the pharmacy technician certificate.
- 5. The pharmacy technician shall retain evidence of their education, training and continuing competency; and further, shall furnish copies of such documentation upon request by the board.
- 6. Sanctions
  - a. The failure of a pharmacy technician to obtain and maintain the education, training and continuing competency described in this Section prior to administering medications to patients shall substantiate a violation of R.S. 37:1241(A)(3), and shall subject the pharmacy technician to disciplinary action by the board.
  - b. The failure of a pharmacy technician to provide documentation of their education, training and continuing competency to administer medications when requested by the board shall substantiate a violation of R.S. 37:1241(A)(22), and shall subject the pharmacy technician to disciplinary action by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182. HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 48:496 (March 2022).

[End of Chapter 9]

# Chapter 11. Pharmacies

# Subchapter A. General Requirements

# §1101. Pharmacy

- A. Qualification. Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescription drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.
- B. Appearance. The applicants, including the pharmacist-in-charge, may be required to personally appear before the board prior to a board decision on the permit application.
- C. Pharmacy Permit.
  - 1. The initial pharmacy permit application shall be completed and signed by the pharmacist-in-charge and the owner of the pharmacy and submitted to the board for approval. An application for a pharmacy permit shall expire one year after the date of receipt in the board office.
  - 2. Renewal. A pharmacy permit that has not been renewed by December 31 of each year shall expire and be null and void.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1310 (October 1997), LR 29:2087 (October 2003), effective January 1, 2004, LR 33:1131 (June 2007).

# §1103. Prescription Department Requirements

- A. A prescription department of a pharmacy shall be maintained in a clean and orderly condition and shall provide sufficient floor space, fixtures, equipment and supplies commensurate with the nature and scope of the pharmacy's practice to ensure that drugs are compounded and dispensed in a dry, well-lighted, climate controlled, and safely enclosed structure.
- B. Restricted. A prescription department is a restricted area.
- C. Prescription Department Plumbing. A sink equipped with hot and cold running water shall be located within the prescription department. A sink located in a pharmacy restroom shall not be sufficient to satisfy this requirement.
- D. Electronic Record Keeping System. An electronic record keeping system shall be utilized in a pharmacy department and shall be a complete, accurate, and readily retrievable prescription record keeping and storage system.
- E. Drug Inventory
  - 1. Storage. The pharmacy shall provide an adequate prescription inventory in order to compound and dispense prescription orders. All areas where drugs are stored shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product information or labeling.
  - Missing or Damaged Inventory. When significant drug inventory is missing or damaged for any reason, the pharmacy owner or pharmacist-in-charge shall file with the board a signed statement of the circumstances of such occurrence and evidence that the appropriate law enforcement authorities were notified as required by law.
- F. Pharmacy Security. The prescription department or the premises housing the prescription department shall be adequately secured by the installation of partitions and secured entrances, which shall be locked by a pharmacist and made inaccessible when the prescription department is closed. The prescription department or any premises housing a prescription department shall be adequately secured by an alarm system.
- G. Emergency Access. An additional key to the prescription department may be maintained in a secure location outside the prescription department for use during an emergency. A log shall be maintained with the key, indicating the name of each non-pharmacist using this key, the date and time of entry, and the nature of the emergency.
- H. References. The current edition of the Louisiana Board of Pharmacy Laws and Regulations shall be maintained and readily available within the prescription department of a pharmacy. The pharmacy shall maintain access to current and appropriate reference materials pertinent to the pharmacy practice, including but not limited to veterinary pharmacy.
- I. Pharmacies hosting medication administration activities, as well as pharmacists administering medications in a location other than a pharmacy, shall comply with the following minimum standards:

- There shall be sufficient staffing available for the pharmacist to administer the medication, supervise any other pharmacy personnel administering medications, and monitor the patient afterward without distraction from other responsibilities.
- 2. To facilitate emergency management of anaphylactic reactions, there shall be adequate supplies of medication and equipment, as well as pre-determined procedures for the arrangement of emergency medical services.
- J. Healthcare Workplace Violence Prevention. The pharmacy shall comply with the provisions of R.S. 40:2199.11 through 40:2199.19 including but not limited to signage, prevention plans, and reporting.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2087 (October 2003), effective January 1, 2004, LR 39:315 (February 2013), amended by the Department of Health, Board of Pharmacy, LR 46:579 (April 2020), LR 47:1642 (November 2021), LR 48:497 (March 2022), LR 49:1556 (September 2023), amended LR 50:1156 (August 2024).

#### §1105. Pharmacist-in-Charge

- A. The opportunity to accept an appointment as the pharmacist-in-charge (PIC) of a pharmacy is a professional privilege. The following requirements are attached to a PIC privilege.
  - 1. The acquisition of the PIC privilege shall require:
    - a. possession of an active Louisiana pharmacist license;
    - b. active pharmacy practice for a minimum of two years under the jurisdiction of any board of pharmacy in the United States; and
    - c. the completion of the affidavit of responsibility and duties described below.
  - 2. The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no less than 20 hours per week during the pharmacy's ordinary course of business. In the event the pharmacy's normal hours of business are less than 20 hours per week the PIC shall be present and practicing at least 50 percent of the normal business hours.
- B. An initial and renewal pharmacy permit application shall designate and identify the licensed pharmacist-incharge.
- C. Authority and Accountability. The pharmacist-in-charge shall be ultimately responsible for complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.
- D. Policy and Procedure Manual. The pharmacist-in-charge shall be responsible for the implementation of policies and procedures regarding quality pharmacy services including drug control, distribution, patient compliance accountability, inspection, and record keeping.
- E. Circumvention. It is a violation of the pharmacy permit for any person to subvert the authority of the pharmacist-in-charge by impeding the management of the prescription department in the compliance of federal and state pharmacy laws and regulations.
- F. Records. The pharmacist-in-charge shall be responsible for the proper maintenance of all prescription records. This necessarily includes electronic prescription records and the system's compliance and capacity to produce the required records.
- G. Recall. The pharmacist-in-charge shall be responsible for the implementation of a recall procedure that can be readily activated to assure patient safety.
- H. Discontinued and Outdated Drugs. The pharmacist-in-charge shall be responsible for the implementation of policies and procedures to ensure that discontinued or outdated drugs, or containers with worn, illegible, or missing labels are withdrawn from the pharmacy inventory.
- I. Change of Pharmacist-in-Charge. Written notice to the board shall be required when the pharmacist-in-charge designation for a pharmacy has changed.
  - 1. The permit holder shall notify the board within 30 days of the prior pharmacist-in-charge's departure date. The permit holder shall designate a new pharmacist-in-charge within 10 days of the departure of the prior pharmacist-in-charge.
  - 2. The new pharmacist-in-charge shall afford the board written notice of his newly designated pharmacist-in-charge status within 30 days of the departure of the prior pharmacist-in-charge.
  - 3. A pharmacist-in-charge who voluntarily leaves a pharmacy shall give written notice to the board and the owner of the permit at least 10 days prior to this voluntary departure, unless replaced in a shorter period of time.

- J. Affidavit of Responsibility and Duties. The designated pharmacist-in-charge shall sign an affidavit on a form supplied by the board indicating his understanding and acceptance of the duties and responsibilities of a pharmacist-in-charge. This document shall be submitted to the board for inclusion in the pharmacist's record in the board office.
- K. A pharmacist shall not hold a pharmacist-in-charge position at more than one pharmacy permit, unless approved by the board.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2088 (October 2003), effective January 1, 2004, LR 38:1239 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:579 (April 2020), LR 47:1643 (November 2021).

## §1107. Pharmacy Operations

- A. The owner of the pharmacy shall employ an appropriate number of professional, technical, and clerical personnel commensurate with the nature and scope of the pharmacy practice. The owner of the pharmacy shall ensure there are a sufficient number of licensed personnel on site when the pharmacy is open to competently and safely perform patient care services and dispense prescriptions accurately.
- B. Minimum Hours of Operation; Business Hours Posted
  - 1. A pharmacy shall be open for business a minimum of 10 hours per week. A pharmacist shall be on duty at all times when the pharmacy is open for business, subject to the provision for the temporary absence of a pharmacist in Section 1109 of this Part.
  - 2. The pharmacy shall post its hours of operation at the building entrance in full public view from outside the premises. Pharmacies holding permits classified as correctional, hospital, institutional, or nuclear shall be exempt from this posting requirement.
- C. No person credentialed by the board may engage in the practice of pharmacy for a period of time longer than six hours without a rest break.
- D. The owner of the pharmacy shall develop plans, policies, and procedures to ensure business continuity in the event of natural or other disasters or emergencies. Such plans, policies, and procedures shall include provisions for continuity of patient care in the event the pharmacy is unable to open for business. The pharmacy shall provide access to such plans, policies, and procedures when requested by the board.
- E. Temporary Closure of Pharmacy in an Emergency
  - 1. When the governor issues or renews a state of emergency pursuant to the Emergency Assistance and Disaster Act of 1993, R.S. 29:721 et seq., or a state of public health emergency pursuant to the Louisiana Health Emergency Powers Act, R.S. 29:760 et seq., or when the pharmacist-in-charge determines it necessary to close the pharmacy for a temporary period of time during an emergency or Act of God, the following provisions shall apply:
    - a. The pharmacy shall notify the board in written form with information as to the anticipated duration of the temporary closure as well as the provisions for continuity of patient care no later than the next business day.
    - b. The pharmacy may establish a secure storage area separate from, but adjoining to, the secured prescription department within which the pharmacy may store prescriptions prepared for delivery to the patient, or his agent or caregiver. In the alternative, but only after receiving approval from the board, the pharmacy may establish a temporary secure storage area separate from and not adjoining the prescription department within which the pharmacy may store prescriptions prepared for delivery to the patient, or his agent or caregiver.
    - c. Access to prescriptions stored in the temporary secure storage area shall be restricted to individuals designated by the pharmacist-in-charge.
    - d. Prepared prescriptions stored in a temporary secure storage area may be delivered to the patient, or his agent or caregiver, whether or not a pharmacist is on duty, but only when so authorized by the pharmacist-in-charge.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1310 (October 1997), amended LR 29:2088 (October 2003), effective January 1, 2004, LR 34:1408 (July 2008), amended by the Department of Health, Board of Pharmacy, LR 47:1643 (November 2021), LR 48:2105 (August 2022), LR 50:34 (January 2024).

#### §1109. Pharmacist Temporary Absence

A. A pharmacist shall be considered to be temporarily absent from the prescription department when not within the confines of the prescription department but remains on-site.

- B. The pharmacist may be temporarily absent from the prescription department for breaks and meal periods without closing the prescription department and removing pharmacy personnel providing the following conditions are met:
  - 1. at least one certified pharmacy technician or pharmacy intern remains in the prescription department;
  - 2. the pharmacist is available for emergencies;
  - 3. the temporary absence does not exceed 30 minutes at a time and a total of 60 minutes in a 12-hour period;
  - 4. the pharmacist reasonably believes that the security of the prescription department will be maintained in his absence; and
  - 5. a notice is posted that includes the following information:
    - a. the fact that the pharmacist is taking a break; and
    - b. the time the pharmacist will return.
- C. If the pharmacist, in his professional judgment, determines it necessary, all personnel shall be removed from the pharmacy and the pharmacy shall be secured for the duration of the temporary absence, and notice shall be posted indicating the pharmacy is closed.
- D. During a temporary absence, certified pharmacy technicians or pharmacy interns may continue to process prescription orders, provided that no orders processed during the pharmacist's temporary absence be removed from the prescription department prior to the final check by the pharmacist.
- E. If the pharmacist is absent less than five minutes from the prescription department, this absence is not considered a "temporary absence" within the meaning of this Chapter and will not require a posted notice, provided the prescription department's security is not compromised.
- F. If at any time the pharmacist deems it necessary to leave the on-site facility, the pharmacy shall be closed in accordance with Section 1111 of this Part.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 27:2237 (December 2001) effective January 1, 2002, LR 29:2088 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:579 (April 2020).

#### §1111. Pharmacist Absence

- A. A pharmacist is considered absent from the prescription department when he is not in the prescription department and is off-site.
- B. When a pharmacist is absent from the prescription department, the prescription department must be securely closed and made inaccessible. A sign shall be displayed in a conspicuous position in front of the prescription department giving notice of closure. The sign shall be at least 8½ x 11 inches with the following wording in black letters at least one inch high: PRESCRIPTION DEPARTMENT CLOSED.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 24:692 (April 1998), LR 29:2089 (October 2003), effective January 1, 2004.

# §1113. Mechanical Drug Dispensing Devices

A. Dispensing of prescription drugs directly to a patient or caregiver by mechanical devices or machine is prohibited. This prohibition shall not apply to automated medication systems as defined and provided for in Chapter 12 of this Part.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:580 (April 2020).

# §1115. Advertising

- A. False, fraudulent, deceptive, or misleading advertising as prohibited by R.S. 37:1241 of the Pharmacy Practice Act and this Section shall include, but is not limited to, any public misrepresentation done or made with the knowledge, whether actual or constructive, that is untrue or illegal, or is said to be done falsely when the meaning is that the party is in fault for its error. Actual or constructive knowledge as used in this context shall include intentionally, negligently, mistakenly, or accidentally representing an untrue fact.
- B. No person shall carry on, conduct, or transact business under a name which contains a part thereof the words "pharmacist", "pharmacy", "apothecary", "apothecary shop", "chemist's shop", "drug store", "druggist", "drugs", or any word or words of similar or like import, or in any manner by advertisement, circular, poster,

- sign, or otherwise describe or refer to a place of business by the terms of "pharmacy", "apothecary", "apothecary shop", "chemist's shop", "drug store", "drugs", or any word or words of similar or like import, unless the place of business is a pharmacy validly permitted by the board.
- C. Pharmacies and pharmacists are prohibited from advertising professional ability, experience, integrity, professional qualifications, or soliciting professional practice by means of providing prescribers of prescriptions with prescription forms imprinted with any material referring to a pharmacy or pharmacist.
- D. No advertising shall include any reference, direct or indirect, to any controlled dangerous substance as provided for in Schedules II, III, IV, or V of <u>R.S. 40:964</u>. The provision of coupons or vouchers for controlled substances through authorized prescribers, which accompany legitimate prescriptions for such controlled substances issued to patients, shall not be prohibited by this Section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1311 (October 1997), amended LR 29:2089 (October 2003), effective January 1, 2004, LR 33:1131 (June 2007), amended by the Department of Health, Board of Pharmacy, LR 46:580 (April 2020).

# Subchapter B. Pharmacy Records

# §1119. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section: Chart Order – a lawful order entered on the electronic or paper chart or medical record of an inpatient or resident of an institutional facility by a practitioner or his licensed healthcare designee for a drug or device and shall be considered a prescription drug order provided it contains the following:

- 1. full name of the patient;
- 2. date of issuance;
- 3. name, strength, and dosage form of the drug prescribed;
- 4. directions for use;
- 5. name of the prescribing practitioner;
- 6. the prescribing practitioner's written or electronic signature or the written or electronic signature of the practitioner's licensed healthcare designee, who shall be a licensed nurse, pharmacist, or physician practicing in a long-term care facility. The licensed healthcare designee shall be authorized to document a chart order in the patient's medical record on behalf of the prescribing practitioner pending the prescribing practitioner's signature, or to communicate a prescription to a pharmacy whether telephonically, by facsimile transmission, or electronically.

Department – the Louisiana Department of Health or its successor.

*Medical Order* – a lawful order of a practitioner that may or may not include a prescription.

Password – a private identification that is created by a user to obtain access to an electronic pharmacy information system.

Personal Identifier – a unique user name or number for identifying and tracking a specific user's access to a pharmacy information system such as Social Security number, user identification number, or employee number. Positive Identification – a method of identifying an individual who prescribes, administers, or dispenses a prescription drug.

- a. A method may not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:
  - i. a manual signature on a hard copy record;
  - ii. a magnetic card reader;
  - iii. a bar code reader;
  - iv. a thumbprint reader or other biometric method;
  - v. a proximity badge reader;
  - vi. a register in which each individual pharmacist dispensing a prescription shall sign a log each day, attesting to the fact that the information entered into the electronic record keeping system has been reviewed that day, and is correct as stated;
  - vii. a printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the prescription drug. The printout must be maintained for two years and made available on request to an agent of the board.
- b. A method relying on a magnetic card reader, a bar code reader, or a proximity badge reader must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

*Prescription* or *Prescription Drug Order* – 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, LR 40:2252 (November 2014), effective January 1, 2015, amended by the Department of Health, Board of Pharmacy, LR 46:580 (April 2020).

# §1121. General Requirements

- A. Requirements.
  - 1. All records relating to the practice of pharmacy shall be uniformly maintained for a period of two years, be readily available, and promptly produced upon request for inspection by an agent of the board during regular business hours.
  - 2. All records required by the laws and regulations of the board shall be provided to the board, or its agents, within 72 hours of request, unless a shorter period is required, as determined by the board or its agent.
  - 3. The failure to produce any pharmacy records requested by the board or its agent within 72 hours of such request shall substantiate a violation of R.S. 37:1241(A)(22).
- B. Accountability. The holder of the pharmacy permit and the pharmacist-in-charge shall account for all prescription drug transactions, consisting of:
  - 1. Acquisition Records invoice receipts of drugs acquired;
  - 2. *Disposition Records* drugs dispensed pursuant to prescription drug orders or chart orders, administered pursuant to medical orders, or distributed pursuant to purchase orders; and
  - 3. *Inventory Records* drugs in current possession.
- C. Retention. Except as provided in Section 1123 of this Part, all records required by this Part and by Louisiana law shall be retained for a minimum of two years from the most recent transaction. The failure to retain such records for at least two years shall substantiate a violation of R.S. 37:1229.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, LR 40:2252 (November 2014), effective January 1, 2015, amended by the Department of Health, Board of Pharmacy, LR 46:580 (April 2020).

# §1123. Records of Prescription Drug Orders and Chart Orders

- A. There shall be positive identification of the pharmacist, intern, technician, or technician candidate responsible for performing all activities related to the practice of pharmacy including, but not limited to:
  - 1. prescription information entered into the pharmacy information system;
  - 2. prospective drug utilization review;
  - 3. prescription dispensing;
  - 4. administration of immunizations.
- B. A pharmacy may use one of the following types of pharmacy information systems:
  - 1. A system that utilizes the original hard copy prescription or chart order to document the initial dispensing, but utilizes a computerized system to dispense refills that does not document the positive identification of the pharmacist responsible for the practice of pharmacy. In order to document positive identification, this system shall require the manual signature or initials of a pharmacist on a hard copy record as specified in Subsection E of this Section.
  - 2. An electronic recordkeeping system that complies with the provisions of <u>21 CFR 1311</u> et seq. and documents the positive identification of the pharmacist responsible for the practice of pharmacy. Such systems shall provide for routine backups at least once per day.
- C. All pharmacy information systems shall be capable of providing immediate retrieval (via display and hard copy printout or other mutually agreeable transfer media) of patient profile information for all prescription drug orders and chart orders dispensed within the previous two years. This information shall include the following minimum data:
  - 1. the original prescription number;
  - 2. date of issuance of the original prescription drug order or chart order by the prescriber;
  - 3. date of dispensing by the pharmacist;
  - 4. full name and address of the patient;
  - 5. full name and address of the prescriber;
  - 6. directions for use;

- 7. the name, strength, dosage form, and quantity of the drug prescribed;
- 8. the quantity dispensed if different from the quantity prescribed;
- 9. the pharmacist responsible for prescription information entered into the computer system, the pharmacist responsible for prospective drug utilization review as defined in Section 515 of this Part, and the pharmacist responsible for dispensing;
- 10. the total number of refills authorized by the prescriber; and
- 11. the refill history of the prescription as defined in Subsection D of this Section.
- D. The refill history of the prescription record maintained in the pharmacy information system shall include, but is not limited to:
  - 1. the prescription number;
  - 2. the name and strength of the drug dispensed;
  - 3. the date of the refill or partial fill;
  - 4. the quantity dispensed;
  - 5. the pharmacist responsible for prospective drug utilization review as defined in Section 515 of this Part, and the pharmacist responsible for dispensing each refill;
  - 6. the total number of refills or partial fills dispensed to date for that prescription order.
- E. The hard copy documentation required pursuant to Paragraph B.1 of this Section shall be provided by each individual pharmacist who makes use of such system by signing a statement attesting to the fact that the prescription information entered into the computer is correct as displayed.
- F. Backup Support System
  - 1. The pharmacy information system shall be capable of being reconstructed in the event of an electronic or computer malfunction or unforeseen accident resulting in the destruction of the system or the information contained therein. To prevent the accidental loss of electronic records, an adequate backup system shall be maintained. Backup support systems shall be updated at least once daily.
  - 2. In the event the pharmacy information system experiences down time, a record of all refills dispensed during such time shall be recorded and then entered into the pharmacy information system as soon as it is available for use. During the time the pharmacy information system is not available, prescription drug orders and chart orders may only be refilled if, in the professional judgment of the pharmacist, the number of refills authorized by the prescriber has not been exceeded.
- G. A pharmacy purging a pharmacy information system of prescription records shall develop a method of recordkeeping capable of providing retrieval (via display, hard copy printout, or other mutually agreeable transfer media) of information for all prescription drug orders or chart orders filled or refilled within the previous two years. This information shall include, at a minimum, the following data:
  - 1. pharmacy name and address;
  - 2. original prescription number;
  - 3. date of issuance of the original prescription drug order or chart order by the prescriber;
  - 4. date of original dispensing by the pharmacist;
  - 5. full name and address of the patient;
  - 6. full name and address of the prescriber;
  - 7. directions for use;
  - 8. name, strength, dosage form, and quantity of the drug prescribed;
  - 9. quantity dispensed if different from the quantity prescribed.
  - 10. total number of refills authorized by the prescriber;
  - 11. total number of refills dispensed to date for that prescription drug order or chart order;
  - 12. date of each refill;
  - 13. name or initials of each individual dispensing pharmacist.
- H. A log shall be maintained of all changes made to a prescription record after the prescription has been dispensed. Such log may be accessible to the pharmacist for review, but shall be protected from being altered in any way. At a minimum, the log shall contain the following information:
  - 1. date and time of change;
  - 2. change(s) made;
  - 3. pharmacist making the change.
- I. Prescription drug orders and chart orders entered into a pharmacy information system but not dispensed shall meet all of the following requirements:
  - 1. the complete prescription information shall be entered in the computer system;
  - 2. the information shall appear in the patient's profile; and
  - 3. there is positive identification, in the pharmacy information system or on the hard copy prescription, of the pharmacist who is responsible for entering the prescription information into the system.

- J. With respect to oral prescriptions received in the pharmacy and then transcribed to written form in the pharmacy, or written prescription drug orders or chart orders received by facsimile in the pharmacy, or written prescription drug orders or chart orders presented to the pharmacy, a pharmacy may use an electronic imaging system to preserve such prescriptions, but only if:
  - 1. the system is capable of capturing, storing, and reproducing the exact image of a prescription, including the reverse side of the prescription form and its annotations;
  - 2. any notes of clarification of and alterations to a prescription shall identify the author and shall be directly associated with the electronic image of the prescription form;
  - 3. the image of the prescription form and any associated notes of clarification to or alterations to a prescription are retained for a period of not less than two years from the date the prescription is last dispensed;
  - 4. policies and procedures for the use of an electronic imaging system are developed, implemented, reviewed, and available for board inspection; and
  - 5. the prescription is not for a controlled dangerous substance.
- K. Filing and Retention of Prescription Forms
  - 1. Written prescription drug order and chart order forms (including transcriptions of verbal prescriptions received in the pharmacy, prescription drug orders or chart orders received by facsimile in the pharmacy, as well as written prescription drug order or chart order forms presented to the pharmacy) shall be assembled and stored in prescription number sequence. Prescriptions for controlled dangerous substances listed in Schedule II shall be filed separately from all other prescriptions. Where multiple medications are ordered on a single prescription form and includes one or more controlled dangerous substances listed in Schedule II, then such forms shall be filed with other Schedule II prescriptions. These original hard copy prescription drug order and chart order forms shall be retained in the prescription department for a minimum of two years following the most recent transaction.
  - 2. For those pharmacies utilizing an electronic imaging system as described in Subsection J of this Section, written prescription drug order forms may be disposed of in a manner which protects the confidentiality of protected health information.
  - 3. Prescription drug order and chart order forms received as an electronic image or electronic facsimile directly within the pharmacy information system shall be retained within the information system for a minimum of two years following the most recent transaction. Further, the pharmacy may produce a hard copy of the prescription drug order form but shall not be required to do so merely for recordkeeping purposes.
  - 4. Electronic prescription drug orders and chart orders, those generated electronically by the prescriber, transmitted electronically to the pharmacy, and then received electronically directly into the pharmacy information system, shall be retained within the information system for a minimum of two years following the most recent transaction. The pharmacy may produce a hard copy of the prescription drug order or chart order, but shall not be required to do so merely for recordkeeping purposes.
- L. Patient Profiles. All pharmacies shall maintain a patient profile system which shall provide for immediate retrieval of information regarding those patients who have received prescriptions from that pharmacy.
  - 1. The dispensing pharmacist shall be responsible for ensuring that a reasonable effort has been made to obtain, document, and maintain at least the following records:
    - .. the patient's data record, which should consist of, but is not limited to, the following information:
      - i. full name of the patient for whom the drug is intended;
      - ii. residential address and telephone number of the patient;
      - iii. patient's date of birth;
      - iv. patient's gender;
      - v. a list of current patient specific data consisting of at least the following:
        - (a) known drug related allergies:
        - (b) previous drug reactions;
        - (c) history of or active chronic conditions or disease states;
        - (d) other drugs and nutritional supplements, including nonprescription drugs used on a routine basis, or devices;
      - vi. the pharmacist's comments relevant to the individual patient's drug therapy, including any other necessary information unique to the specific patient or drug;
    - b. The patient's drug therapy record, which shall contain at least the following information for all the prescription drug orders and chart orders that were filled at the pharmacy:
      - i. name and strength of the drug or device;
      - ii. prescription number;
      - iii. quantity dispensed;

- iv. date dispensed;
- v. name of the prescriber;
- vi. directions for use;
- c. any information that is given to the pharmacist by the patient or caregiver to complete the patient data record shall be presumed to be accurate, unless there is reasonable cause to believe the information is inaccurate.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23:1312 (October 1997), amended LR 29:2090 (October 2003), effective January 1, 2004, LR 36:755 (April 2010), LR 40:2253 (November 2014), effective January 1, 2015, amended by the Department of Health, Board of Pharmacy, LR 46:580 (April 2020), LR 47:1643 (November 2021).

# §1124. Records of Pharmacy Services for Patients in Licensed Healthcare Facilities Other than Hospitals

#### A. Definitions

Electronic Drug Record Keeping System – a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.

*Inpatient* – a person receiving health care services within a healthcare facility other than a hospital licensed by the department.

Password – a private identification that is created by a user to obtain access to an electronic drug record keeping system.

*Personal Identifier* – a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as Social Security number, user identification number, or employee number.

Positive Identification -

- a. has the same meaning as defined in Section 1119 of this Chapter, except that a specific facility having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for the prescribing and administration of a drug, provided the pharmacist-in-charge has determined:
  - i. adequate audit controls are in place to detect and deter drug diversion;
  - ii. adequate access controls are in place to assure the identity of the user and to assign accountability of the user for any drug transaction;
  - iii. adequate safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;
  - iv. an ongoing quality assurance program is in place to ensure that Clauses I through iii of this term are being fulfilled and reviewed; and
  - v. appropriate policies and procedures are in place to address Clauses i through iv of this term;
- b. all of the above notwithstanding, however, positive identification as defined in Section 1119 of this Chapter shall always be used to document the:
  - i. dispensing, compounding, or prepackaging of a drug;
  - ii. removal and possession of a controlled substance to administer to a patient; and
  - iii. waste of a controlled substance.
- B. Drug Distribution and Control. The pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient administration and management of drugs.
  - 1. Procedure Manual. The pharmacist-in-charge shall maintain defined procedures for the safe and efficient distribution of medications and pharmacy care. A current copy of the manual shall be available for board inspection upon request.
  - 2. Inventories. The pharmacist-in-charge shall be responsible for the performance of an annual inventory of all controlled dangerous substances within his span of control, in compliance with the provisions of Section 2733 of this Part.
  - 3. Records. The pharmacist-in-charge shall be responsible for maintaining the following records:
    - a. record of all drugs procured, the quantity received, and the name, address and wholesale distributor license number of the person from whom the drugs were procured;
    - b. all drug orders and records relating to the practice of pharmacy:
      - i. records of drugs dispensed shall include, but are not limited to:
        - (a) the name, strength, and quantity of drugs dispensed;

- (b) the date of dispensing;
- (c) the name of the inpatient to whom, or for whose use, the drug was dispensed; and
- (d) positive identification of all pharmacists involved in the dispensing;
- ii. all other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:
  - (a) the name of the inpatient to whom, or for whose benefit, the activity was performed;
  - (b) the nature of the pharmacy practice activity performed;
  - (c) the results of the activity, if applicable; and
  - (d) positive identification of all pharmacists involved in the activity; identifying the function performed by each pharmacist.
- iii. records of drugs dispensed to patients for use outside the facility shall be maintained in compliance with Section 1123 of this Chapter.
- c. a record of all drugs compounded or prepackaged for use only within a healthcare facility, which shall include at least the following:
  - i. name of drug, strength, quantity, and dosage form;
  - ii. manufacturer's or distributor's control number (except for patient-specific sterile compounded preparations);
  - iii. manufacturer's or distributor's name, if a generic drug is used;
  - iv. pharmacy control number;
  - v. manufacturer's or distributor's expiration date (except for patient-specific sterile compounded preparations);
  - vi. pharmacy's expiration date or beyond-use date;
  - vii. identification of the licensed person responsible for the compounding or prepackaging of the drug;
- d. a record of the distribution of drugs to patient care areas and other areas of the facility held for administration, which shall include at least the following:
  - i. the name, strength, dosage form, and amount of the drug distributed;
  - ii. the area receiving the drug;
  - iii. the date distributed;
  - iv. identification of the individual receiving the drug if it is a controlled dangerous substance;
  - v. the area of the facility receiving the controlled dangerous substance shall make a record of all such drugs administered to patients. Such records shall include at least the following:
    - (a) name of the patient;
    - (b) name, dosage form, and strength when applicable of the drug;
    - (c) date and time the drug was administered;
    - (d) quantity administered;
    - (e) positive identification of the personnel administering the drug;
- e. a log that shall be maintained of all changes made to a drug record in an electronic drug recordkeeping system after a drug transaction has been made. The log shall contain at least, but is not limited, to the following:
  - i. date and time of change;
  - ii. changes made;
  - iii. person making the change.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 40:2255 (November 2014), effective January 1, 2015, amended by the Department of Health, Board of Pharmacy, LR 46:582 (April 2020), repromulgated LR 46:694 (May 2020).

# §1125. Security and Confidentiality

- A. The holder of the pharmacy permit shall provide adequate safeguards against improper, illegal, or unauthorized manipulation or alteration of any records in the pharmacy information system.
- B. A pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential information. If confidential health information is not transmitted directly between a pharmacist and a practitioner, but is transmitted through a data communications device, the confidential health information may not be accessed, maintained, or altered by the operator of the data communications device. Confidential information is privileged and may be released only subject to federal privacy laws and regulations, and subject to applicable Louisiana statutes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182. HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 23.1312, (October 1997), amended LR 29:2091 (October 2003), effective January 1, 2004, LR 40:2256 (November 2014), effective January 1, 2015.

# §1129. Louisiana Uniform Prescription Drug Prior Authorization Form; Requirements; Referral for Enforcement

- A. A prescriber or pharmacy required to obtain prior authorization from a third party payor shall complete the Louisiana Uniform Prescription Drug Prior Authorization Form referenced below in Section 1130, either in written form or its electronic equivalent.
- B. In the event a third party payor demands the completion of an alternative authorization process, the prescriber or pharmacy shall refer the demand to the appropriate enforcement agency.
  - 1. If the demand is made by a Medicaid managed care organization, the prescriber or pharmacy shall refer the demand to the Dept. of Health.
  - 2. If the demand is made by any other third party payor, the prescriber or pharmacy shall refer the demand to the Dept. of Insurance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:1006.1(C) and 46:460.33(B). HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 44:2157 (December 2018), effective January 1, 2019.

# §1130. Louisiana Uniform Prescription Drug Prior Authorization Form

[The two-paged form begins at the top of the next page.]

# LOUISIANA UNIFORM PRESCRIPTION DRUG PRIOR AUTHORIZATION FORM

SECTION I — SUBM	<u>ISSION</u>									
Submitted to:					Phone:		Fax:			Date:
SECTION II — PRES	CRIBER IN	NFORMATIO	N							
Last Name, First Name MI:					NPI# or Plan Provider #: Special					
Address:				City:	City:				State:	ZIP Code:
Phone: Fax:				Office Co	Office Contact Name:			Contact Phone:		
SECTION III — PAT	IENT INFO	ORMATION								
				DOB:	OOB: Phone:			_ =	Male Other	Female Unknown
Address:				City:					State:	ZIP Code:
Plan Name (if differe	ent from S	ection I):	Memb	per or Medi	icaid ID #:	Plan Provider II	D:			
Patient is currently a hospital inpatient getting ready for discharge? Yes No Date of Discharge: Patient is being discharged from a psychiatric facility? Yes No Date of Discharge: Patient is being discharged from a residential substance use facility? Yes No Date of Discharge: Patient is a long-term care resident? Yes No If yes, name and phone number: EPSDT Support Coordinator contact information, if applicable:										
SECTION IV — PRES	SCRIPTIO	n Drug In	FORMATI	ION						
Requested Drug Nam	ie:									
Strength: Dosage Form									on/Start Date:	
To the best of your k			ation is: _			tial request herapy/Reautho	orization	request		
HCPCS/CPT-4 Code			NDC#:_			_Dose Per Admir	nistratio	n:		
Other Codes:										
Will patient receive		in the phys								
SECTION V DATE	ENIT CLIN	UCAL INFOR	DM ATION	,	<u> </u>					
SECTION V — PATIENT CLINICAL INFORMATION  Primary diagnosis relevant to this request:							ICD-10 Diagnosis Code			Date Diagnosed:
Secondary diagnosis relevant to this request:							ICD-10 Diagnosis Code:		Code:	Date Diagnosed:
For pain-related diag For postoperative pa			Acu : Date	te of Surgery_	_Chronic					
Pertinent laboratory	values ar	nd dates (at	tach or lis	t below):						
Date				Name	Name of Test			Value		
		1								

SEC	CTION V	I - This S	Section For Opioid	l Medicatio	ns Only							
Doe	s the quan	tity reque				YesNo (If yes, provide jus	tification below.)					
	ulative dai	-				, N. //C	·r· · · · · · · · · · · · · · · · · · ·					
Doe	s cumulativ	ve daily M	ME exceed the daily	max MME al	llowed?	esNo (If yes, provide justi	fication below.)					
SQ	YES (True)	NO (False)	THE PRESCRIBER ATTESTS TO THE FOLLOWING:									
PIOI			A. A complete assessment for pain and function was performed for this patient.									
ING OI			B. The patient has been <b>screened for substance abuse / opioid dependence</b> . (Not required for recipients in long-term care facility.)									
АСТІ			C. The <b>PMP</b> will be accessed <b>each</b> time a controlled prescription is written for this patient.									
-ONG-				D. A <b>treatment plan</b> which includes current and previous goals of therapy for both pain and function has been developed for this patient.								
SHORT AND LONG-ACTING OPIOIDS			E. <b>Criteria</b> for failure of the opioid trial and for stopping or continuing the opioid has been established and explained to the patient.									
ORT			F. Benefits and potential harms of opioid use have been discussed with this patient.									
SH			G. An <b>Opioid Treatment Agreement</b> signed by both the patient and prescriber is on file. (Not required for recipients in long-term care facility.)									
IDS	H. The patient requires continuous <b>around the clock</b> analgesic therapy for which alternative treatment options have been inadequate or have not been tolerated.											
LONG-ACTING OPIOIDS	Patient previously utilized at least two weeks of short-acting opioids for this condition. Please enter drug(s),											
NG (			· ·			ic/non-pharmacologic treatment ute pain, mild pain, or pain that i						
ACTI			an extended per	iod of time.								
NG.				cation has <b>not</b> been prescribed for use as an as-needed (PRN) analgesic. ribing information for requested product has been <b>thoroughly reviewed</b> by prescriber.								
2			L. Prescribing infor	mation for rec	questeu product	nas been thoroughly reviewed b	y prescriber.					
			OVE (A-L), PLEASE EXP		· · · · · · · · · · · · · · · · · · ·	N 1 (	1. (1					
SEC	TION VI			narmacolog	gic treatment(	s) used for this diagnosis (	-					
Drug name			me 	Strength	Frequency	Dates Started and Stopped or Approximate Duration						
Dru	g Allergies:					Height (if applicable):	Weight (if applicable):					
						plan's pre-requisite medicationNo (If yes, please explai						
			STIFICATION (SI				<u> </u>					
		ii jee	7111611(01		<b>C110110</b> )							
By signing this request, the prescriber attests that the information provided herein is true and accurate to the best of his/her knowledge. Also, by signing and submitting this request form, the prescriber attests to statements in the 'Attestation'												
			specific to this requ			Date						
Sig	nature of P	rescriber:				Date:						

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:1006.1(C) and 46:460.33(B). HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 44:2157 (December 2018), effective January 1, 2019.

# **Subchapter C. Pharmacy Opening, Closing, Change of Ownership, and Change of Location Procedures**

#### §1131. Pharmacy Opening Procedures

- A. The board has established the following procedures as a prerequisite to the opening of any pharmacy:
  - 1. Application Form. The applicant shall obtain the appropriate application form(s) from the board. The completed form(s) shall be signed by the pharmacist-in-charge and returned to the board office, with appropriate fees, not less than 30 days prior to the anticipated opening of the pharmacy.
  - 2. Inspection. After the board has reviewed and approved the application, a board compliance officer shall conduct an on-site inspection of the premises.
  - Compliance. Upon receipt of satisfactory evidence that the applicant is in complete compliance, the board shall issue a pharmacy permit and, if requested, a Louisiana Controlled Dangerous Substance License

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 47:1643 (November 2021).

# §1133. Pharmacy Closing Procedures

- A. A pharmacy permit holder shall notify the public and the board prior to discontinuing a prescription department operation, or upon petitioning for bankruptcy.
  - 1. Public Notice. The holder of a pharmacy permit shall post a closing notice in a conspicuous place in the front of the prescription department, and at all public entrance doors to the pharmacy. The closing notice to the public shall be posted not less than 10 days prior to the anticipated date of closure, and the notice shall contain the following minimum information:
    - a. the anticipated date of closure of the prescription department;
    - b. the anticipated date of transfer or relocation of prescription files, if different than closure date;
    - c. the name and address of the pharmacy to which the prescription files will be transferred; and
    - d. a statement that if a patient objects to the transfer of their prescription files to the intended recipient pharmacy, the patient shall make alternative arrangements for the transfer of their prescription files to another pharmacy prior to the anticipated file transfer date.
  - 2. Board Notice. The holder of a pharmacy permit shall send written notice to the board not less than 10 days prior to the anticipate date of closure, and the notice shall include the following minimum information:
    - a. the anticipated date of closure of the prescription department;
    - b. the name and address of the permitted pharmacy operating within a reasonably close proximity of the closing pharmacy that shall be the custodian of the transferred prescription files; and
    - c. any prescription drug sale or transfer, with a complete drug inventory including recipient's name and address and/or seizure action, sequestration, executory process, public auction, liquidation, creditor assignment, and bankruptcy.
  - 3. Disposition of Inventory
    - a. Drugs Listed in Schedule II. These drugs shall be either returned to the supplier or transferred to an authorized registrant, accompanied by an executed <u>DEA Form 222</u>, or its successor. Alternatively, these drugs shall be inventoried on the <u>DEA Form 41</u> (Registrants Inventory of Drugs Surrendered), or its successor, and then either returned to the regional DEA office, or destroyed pursuant to permission from the DEA or agent of the board. The permit holder shall retain triplicate copies of returns, transfers, and/or destructions.
    - b. Drugs Listed in Schedules III, IV, or V. These drugs shall be either returned to the supplier or transferred to an authorized registrant, accompanied by appropriate inventory records. Alternatively, these drugs shall be inventoried on the <u>DEA Form 41</u>, or its successor, and then either returned to the regional DEA office, or destroyed pursuant to permission from the DEA or agent of the board.
    - c. All Other Prescription Drugs. These drugs shall be returned to the supplier, transferred to an authorized registrant, or destroyed.
  - 4. Surrender of Pharmacy Permit and Louisiana Controlled Dangerous Substance License. The holder of the permit and license shall surrender same to the board upon closing, accompanied by written confirmation

of the:

- a. surrender of unused DEA order forms and the DEA registration certificate to the regional DEA office with a memorandum indicating the closing date of the prescription department;
- b. location of applicable records of controlled dangerous substance and other prescription drugs, order forms, inventories, acquisitions, and purchase records, with commitment to store such records for not less than two years, and to make such records available for inspection by an agent of the board; and
- c. removal of all pharmacy signage from the property.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2091 (October 2003), effective January 1, 2004.

#### §1135. Pharmacy Change of Ownership Procedures

- A. A pharmacy permit is not transferable.
- B. A new application shall be filed and a new permit obtained when a change in the identity of the natural person, partnership, or business entity which directly holds the permit has occurred or there is a change in the person or entity's Federal Employer Identification Number (FEIN).
- C. The new owner shall submit an application to the board office at least 15 days before closing the transfer of ownership interests of said business.
- D. An application for a new pharmacy permit shall include the direct and first indirect level of ownership information. Any change in the first indirect level of ownership of 20 percent or more must be reported to the board within 30 days of the change.
- E. Nothing in this Section shall prohibit an entity from applying for a new pharmacy permit in order to separate itself from actions which may have been committed by the previous ownership under the existing pharmacy permit.
- F. The continued operation of a pharmacy permit subsequent to a change of ownership, without submission of an application to the board office, may substantiate a violation of R.S. 37:1221.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2092 (October 2003), effective January 1, 2004, amended LR 33:1131 (June 2007), amended by the Department of Health, Board of Pharmacy, LR 49:1558 (September 2023).

# §1137. Pharmacy Change of Location Procedures

- A. The board has established the following procedures for changing the location of any pharmacy that does not involve a change of ownership or divestiture of that pharmacy:
  - 1. The permit holder shall notify the board in writing prior to relocating a prescription department operation.
  - 2. The proper notice procedures for the relocation shall include the notice requirements applicable to pharmacy closing procedures noted in this Subpart. However, a permit cancellation is not required for a permit holder that is moving to a location in reasonably close proximity to the original location and planning to continue pharmacy operations without a transfer of ownership. The permit holder shall notify the board for the proper re-designation of permit address and re-issuance of that same permit.
  - 3. Inspection. A board compliance officer shall conduct an on-site inspection of the premises following receipt of written notice in the board office and prior to the opening of a prescription department in a new location.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2092 (October 2003), effective January 1, 2004.

#### Subchapter D. Off-Site Services

# §1139. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section, unless the context clearly indicates otherwise.

Centralized Prescription Dispensing – the fulfillment by one permitted pharmacy of a request from another permitted pharmacy to fill or refill a prescription drug order.

*On-Site Pharmacy* – a permitted pharmacy which utilizes centralized prescription dispensing services from a remote dispenser or remote processing services from a remote processor.

*Remote Dispenser* – a Louisiana-permitted pharmacy which provides centralized prescription dispensing services for another permitted pharmacy in Louisiana.

Remote Processing Services – the processing of a medical order or prescription drug order by one permitted pharmacy on behalf of another permitted pharmacy, including:

- a. receipt, interpretation, or clarification of an order;
- b. data entry and information transfer;
- c. interpretation of clinical data;
- d. performance of drug utilization review; and
- e. provision of drug information concerning a patient's drug therapy; provided, however, that remote processing does not include the physical preparation or physical transfer of drugs.

*Remote Processor* – a Louisiana-permitted pharmacy which provides remote processing services for another permitted pharmacy in Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1131 (June 2007), amended LR 39:313 (February 2013).

# §1141. Centralized Prescription Dispensing

#### A. General Requirements

- 1. An on-site pharmacy may obtain centralized prescription dispensing services from a remote dispenser provided the pharmacies:
  - a. have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and
  - b. share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to provide the requested services.
- 2. All drugs dispensed to a patient that have been dispensed by a remote dispenser shall bear a label containing an identifiable code that provides a complete audit trail of the dispensing of the drug and pharmacy primary care activities.

#### B. Policies and Procedures

- 1. On-site pharmacies and remote dispensers engaging in the acquisition or provision of centralized dispensing services shall maintain a policy and procedure manual for reference by all personnel; it shall be made available for inspection and copying by the board.
- 2. At a minimum, the manual shall include policies for:
  - a. a description of how the parties will comply with federal and state laws and regulations;
  - b. the maintenance of appropriate records to identify the responsible pharmacist(s) in the dispensing and counseling processes;
  - c. the maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process;
  - d. the maintenance of a mechanism to identify on the prescription label all pharmacies involved in the dispensing of the prescription drug order; and
  - e. the provision of adequate security to protect the confidentiality and integrity of patient information and to prevent its illegal use or disclosure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1131 (June 2007).

### §1143. Remote Processing of Medical Orders or Prescription Drug Orders

#### A. General Requirements

- 1. An on-site pharmacy may obtain remote processing services from a remote processor provided the pharmacies:
  - a. have the same owner or have entered into a written contract or agreement that outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws, rules, and regulations; and
  - b. share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to provide the requested services.

- 2. A contract or agreement for remote processing services shall not relieve the on-site pharmacy from employing or contracting with a pharmacist to provide routine pharmacy services. The activities authorized by this Section are intended to supplement pharmacy services and are not intended to eliminate the need for an on-site pharmacy or pharmacist.
  - a. In the event the pharmacy soliciting remote processing services is located within a hospital with more than 100 occupied beds, there shall be at least one pharmacist on duty at that hospital at all times, and any remote processing services provided to that pharmacy shall be supplemental in nature.

#### B. Access to Patient Information

- 1. The pharmacist at the remote processor shall have secure electronic access to the on-site pharmacy's patient information system and to all other electronic systems directly involved with the preparation of prescriptions that the on-site pharmacist has access to when the on-site pharmacy is operating. The pharmacist at the remote processor shall receive training in the use of the on-site pharmacy's electronic systems.
- 2. If an on-site pharmacy is not able to provide remote electronic access to the remote processor, both pharmacies shall have appropriate technology to allow access to the required patient information.

#### C. Policies and Procedures

- 1. On-site pharmacies and remote processors engaging in the acquisition or provision of remote processing services shall maintain a policy and procedure manual for reference by all personnel; it shall be available for inspection and copying by the board.
- 2. At a minimum, the manual shall include policies and procedures for:
  - a. identification of the responsibilities of each of the pharmacies;
  - b. protection of the integrity and confidentiality of patient information;
  - c. maintenance of appropriate records to identify the name, initials, or unique identification code of each pharmacist performing processing functions, the specific services performed, and the date of such services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1132 (June 2007), amended LR 38:1240 (May 2012), LR 39:313 (February 2013), LR 41:2148 (October 2015).

# §1145. Remote Access to Prescription Drug Orders, Medical Orders, and Chart Orders

- A. Notwithstanding any provisions of rules to the contrary, nothing shall prohibit a Louisiana-licensed pharmacist who is an employee of or under contract with a pharmacy in Louisiana from accessing that pharmacy's dispensing information system from a location other than the pharmacy in order to process prescription drug orders, medical orders, or chart orders, but only when all of the following conditions are satisfied:
  - 1. the pharmacy establishes controls to protect the privacy and accuracy of confidential records;
  - 2. the pharmacist does not engage in the receiving of written prescription drug orders or medical orders or chart orders or the maintenance of such orders; and
  - 3. no part of the pharmacy's dispensing information system is duplicated, downloaded, or removed from the pharmacy's dispensing information system.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 46:582 (April 2020).

#### §1147. Starter Doses for Patients in Licensed Healthcare Facilities

#### A. Definitions

Starter Dose Order – a prescription drug order or chart order transmitted by a vendor pharmacy to a starter dose pharmacy for the purpose of obtaining medication for a patient in a licensed health care facility.

Starter Dose Pharmacy – a Louisiana-licensed pharmacy that dispenses a starter dose of medication to a patient in a licensed health care facility pursuant to a starter dose order.

*Vendor Pharmacy* – a Louisiana-licensed pharmacy which has a contract with a licensed health care facility to dispense medications to patients within that facility.

- B. A vendor pharmacy may share a chart order with a starter dose pharmacy without the necessity of transferring such order, for the purpose of authorizing the starter dose pharmacy to dispense starter doses of medications to a patient in a licensed health care facility under the following circumstances:
  - 1. the vendor pharmacy has secured authorization from the facility to utilize a starter dose pharmacy;
  - 2. the vendor pharmacy is in possession of a valid chart order and is unable to furnish the medication ordered in a timely manner; and
  - 3. the vendor pharmacy and starter dose pharmacy maintain records of all chart orders and starter dose

orders for a period of not less than two years following the date of transmission of such orders.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182. HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 46:582 (April 2020).

[End of Chapter 11]

# **Chapter 12. Automated Medication Systems**

# §1201. Definitions

*Healthcare Setting* – a place where healthcare services are rendered on a routine basis by credentialed healthcare professionals.

Remote Dispensing System – a profile-driven automated medication dispensing system employing bidirectional audio-visual technology to facilitate pharmacist communication with a patient or caregiver.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000, amended by the Department of Health, Board of Pharmacy, LR 47:241 (February 2021).

# §1203. Automated Medication System Registration

#### A. Requirement for Registration

- 1. A pharmacy intending to supply medications for use within an automated medication system, as defined at <u>R.S. 37:1164</u>, shall obtain an automated medication system (AMS) registration prior to engaging in such activity.
- 2. The placement of medications within an automated medication system in the absence of an AMS registration shall substantiate a violation of R.S. 37:1241(A)(12) and shall subject the pharmacy to disciplinary action by the board.
- 3. A pharmacy intending to supply controlled substances for use within an automated medication system shall obtain a controlled dangerous substance (CDS) license in addition to the AMS registration. The pharmacy shall also obtain a federal registration from the U.S. Drug Enforcement Administration (DEA) prior to placing controlled substances within the automated medication system.
- 4. The placement of controlled substances within an automated medication system in the absence of an AMS registration, CDS license, and DEA registration shall substantiate a violation of R.S. 37:1241(A)(12) and R.S. 40:973 and shall subject the pharmacy to disciplinary action by the board.
- 5. The operation of a remote dispensing system without an AMS registration shall substantiate a violation of R.S. 37:1241(A)(12) and shall subject the pharmacy to disciplinary action by the board.

#### B. Eligibility for Registration; Exemption

- 1. A pharmacy intending to supply medications for use within an automated medication system may do so when the AMS is placed at any of the following locations:
  - a. within a facility in possession of a controlled dangerous substance license issued by the board.
  - b. within a hospital or other institutional facility in possession of an operating license issued by the state department of health.
  - c. within a detention or correctional facility operated by or under contract with the state department of public safety and corrections or other local governmental entity.
- 2. A pharmacy may operate a remote dispensing system when the system is placed within a healthcare setting where the pharmacist-in-charge can ensure the security and environmental integrity of the medications and devices placed within the system as well as the security and confidentiality of the protected health information used therein.
- 3. A pharmacy intending to supply medications for use within an AMS which is placed within the building housing that pharmacy shall not be required to obtain an AMS registration; however, the pharmacist-in-charge of the pharmacy shall be responsible for compliance with the operational standards in this Chapter.

#### C. Application for Initial Issuance of Registration

- 1. The board shall develop an application form suitable for the AMS registration. The board may revise that application form on its own initiative in order to collect the information it deems necessary to properly evaluate an applicant.
- 2. The application shall be accompanied by payment of the registration fee authorized by R.S. 37:1184<sup>1</sup>.
- 3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
- 4. The submission of a false or fraudulent application shall substantiate a violation of <u>R.S. 37:1241(A)(2)</u> and shall subject the applicant to disciplinary action by the board.
- 5. When determined appropriate by the board, the applicant may be required to meet with a committee or agent of the board prior to the issuance of the registration.

#### D. Maintenance of Registration

1. A registration shall be valid only for the pharmacy to which it was issued and the physical location of the AMS identified on the application. The registration shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the registration be valid for any premises other than the

- physical location for which it was issued.
- 2. A duplicate or replacement registration shall be issued upon the written request of the owner of the registration and payment of the fee authorized by R.S. 37:1184<sup>1</sup>. A duplicate or replacement registration shall be marked as such, and it shall not serve or be used as an additional or second registration.
- 3. In the event a pharmacy intends to relocate an automated medication system to a different address, the pharmacy shall notify the board of its intent to do so, providing both current and new addresses. A change in business address may require an inspection by the board or its designee.

#### E. Application for Renewal of Registration

- 1. The pharmacy shall complete an application for the renewal of the registration and submit it to the board prior to the expiration date of the registration. The application shall be accompanied by the fee authorized by R.S. 37:1184<sup>1</sup>.
- 2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
- 3. An AMS registration not renewed by the expiration date shall be classified as expired. The operation of an automated medication system with an expired registration shall substantiate a violation of R.S. 37:1241(A)(12) and shall subject the pharmacy to disciplinary action by the board.

# F. Relinquishment of Registration

- In the event a pharmacy intends to cease supplying medications or devices to an automated medication system, it shall relinquish the registration to the board no later than 10 days following the effective date of such decision.
- 2. A pharmacy may not transfer a registration to another pharmacy.
- G. Application for Reinstatement of Suspended or Revoked Registration
  - 1. An application for the reinstatement of an AMS registration previously suspended or revoked by the board may only be approved in compliance with <u>R.S. 37:1249</u>.
  - 2. The applicant shall complete an application form for this specific purpose supplied by the board and shall attach any documentation and fees identified in R.S. 37:1184<sup>1</sup>.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000, amended LR 38:1235 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 47:241 (February 2021).

# §1205. Pharmacist-in-Charge Responsibilities

- A. The pharmacist-in-charge shall be a Louisiana-licensed pharmacist with the following responsibilities:
  - assuring that the system is in good working order and accurately provides the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards.
  - 2. establishment of a quality assurance program prior to implementation of a system and the supervision of an ongoing quality assurance program that monitors appropriate use and performance of a system, which is evidenced by policies and procedures developed by the pharmacist-in-charge.
  - 3. define access to the system in policy and procedures of the pharmacy, in compliance with state and federal regulations.
  - 4. assign, discontinue, or change access to the system.
  - 5. ensure that access to the medications complies with state and federal regulations as applicable.
  - 6. ensure that the system is stocked and restocked accurately and in accordance with established pharmacy policies and procedures.
  - 7. maintain or have access to all records of documentation specified in this Chapter for two years or as otherwise required by law.
  - 8. continuous monitoring and documentation of temperature in the drug storage areas including a mechanism to alert the pharmacist when defined parameters are out of range as well as an action plan to address such excursions. A pharmacy's failure to document the integrity of the drug supply or remediate for excursions as appropriate shall substantiate a violation of R.S. 37:1241(A)(18) and shall subject the pharmacy to disciplinary action by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000, amended by the Department of Health, Board of Pharmacy, LR 47:241 (February 2021).

# §1207. Pharmacist Review

A. System shall be used in settings that ensure medication orders are reviewed by a pharmacist prior to administration and in accordance with established policies and procedures and good pharmacy practice. A policy and procedure shall be adopted for non-profile driven systems to retrospectively review medication orders which cannot be reviewed prior to medication administration.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1271 (June 2000) effective July 1, 2000, amended by the Department of Health, Board of Pharmacy, LR 47:242 (February 2021).

#### §1211. Documentation

- A. Documentation as to type of equipment, serial number, content, policies and procedures and location shall be maintained in the pharmacy for review by the board. Such documentation shall include, but is not limited to:
  - 1. name, address, and permit number of the pharmacy and the location where the system is operational;
  - 2. manufacturer's name and model;
  - 3. quality assurance policies and procedures to determine continued appropriate use and performance of the system;
  - 4. policies and procedures for system operation, safety, security, accuracy, patient confidentiality, access, controlled substances, data retention, definitions, downtime procedures, emergency or first dose procedures, inspection, installation requirements, maintenance security, quality assurance, medication inventory, staff education and training, system set-up, and malfunction procedures; and
  - 5. security procedures sufficient to prevent unauthorized access or use, prevent the illegal use or disclosure of protected health information, and comply with any applicable federal or state regulations.
- B. A current copy of all pharmacy policies and procedures related to the use of the system shall be maintained at all locations where the system is being used.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1272 (June 2000) effective July 1, 2000, amended by the Department of Health, Board of Pharmacy, LR 47:242 (February 2021).

# §1213. Records

- A. Records and electronic data kept by the system shall meet the following requirements:
  - 1. All events involving access to the contents of the system shall be recorded electronically.
  - 2. In the event controlled substances are stored in the system, the records shall include the positive identification (as defined in §1119 of this Part) of the personnel retrieving and administering the controlled substances to the patient.
  - 3. These internal records shall be maintained for one year by the pharmacist-in-charge and shall be readily available to the board. Such records shall include:
    - a. identity of system accessed;
    - b. identification of the individual accessing the system;
    - c. type of transaction:
    - d. name, strength, dosage form, and quantity of the drug accessed;
    - e. name or identification number of the patient for whom the drug was ordered;
    - f. identification of the person stocking or restocking the medications in the system; and
    - g. such additional information as the pharmacist-in-charge may deem necessary.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.A.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1273 (June 2000) effective July 1, 2000, amended LR 40:2256 (November 2014), effective January 1, 2015, amended by the Department of Health, Board of Pharmacy, LR 47:242 (February 2021).

#### §1217. Stocking and Restocking; Electronic Product Verification

- A. The stocking and restocking of medications and devices within an automated medication system shall be performed by a pharmacist, or in the alternative, a pharmacy intern, pharmacy technician, or pharmacy technician candidate under the supervision of a pharmacist.
- B. When the pharmacy employs electronic product verification procedures as described within this Section, the stocking and restocking of medications and devices within an automated medication system may be performed by other licensed personnel approved by the pharmacist-in-charge without the necessity of direct pharmacist supervision.

- 1. A bar code verification, electronic verification, or similar verification process which prohibits any human intervention following pharmacist verification of the product may be utilized to assure the correct selection of drugs to be placed into an automated medication system.
- 2. The use of a bar code, electronic verification, or similar verification process shall require an initial quality assurance validation followed by ongoing quality assurance reviews at intervals no greater than 90 days since the previous review, all conducted by a pharmacist.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182(A). HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 26:1273 (June 2000) effective July 1, 2000, amended LR 41:1488 (August 2015), amended by the Department of Health, Board of Pharmacy, LR 47:243 (February 2021).

#### [End of Chapter 12]

#### Note:

<sup>&</sup>lt;sup>1</sup> The statutory list of fees in R.S. 37:1184 is no longer current. The current list of fees is found in Chapter 1 of the administrative code, more specifically in Section 115. The board has not yet revised this chapter to remove the obsolete citations.

# **Chapter 13. Community Pharmacy**

# §1301. Definition

A. A *community pharmacy* is a pharmacy located in a non-institutional environment, and is licensed by the board to conduct professional pharmacy practice activities in the state of Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2092 (October 2003), effective January 1, 2004.

# §1303. Permit

A. A community pharmacy permit shall be required to operate a pharmacy in this state, and to dispense prescription drugs to patients in Louisiana. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2092 (October 2003), effective January 1, 2004.

# §1305. Compliance

A. A community pharmacy shall comply with all applicable federal and state pharmacy laws and regulations, including Chapter 11 of these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2092 (October 2003), effective January 1, 2004.

[End of Chapter 13]

# **Chapter 15. Hospital Pharmacy**

#### §1501. Cross References

A. For all regulations that apply to permitted hospital pharmacies concerning pharmacy practices and records not specifically stated in this Chapter, refer to Chapters 11 and 25 of this Part.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:808 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, LR 38:1235 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:582 (April 2020).

# §1503. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section: *CFR* – Code of Federal Regulations.

*Electronic Drug Record Keeping System* – a system of storing drug records electronically and capturing the positive identification of the person responsible for a specific drug transaction including, but not limited to, the prescribing, administering, or dispensing of a drug.

Hospital Off-Site Satellite Pharmacy – a pharmacy located within a hospital licensed by the Louisiana Department of Health, or its successor, the location of which is physically separate from the location of the provider pharmacy. Hospital Patient – a person receiving health care services within a hospital facility, or an animal receiving veterinary care within a veterinary teaching hospital owned or operated by a public university in this state.

Hospital Pharmacy – a pharmacy department permitted by the board and located in a hospital licensed pursuant to R.S. 40:2100 et seq or in a veterinary teaching hospital owned or operated by a public university in this state. For the purposes of this Chapter, a hospital pharmacy is one example of a primary care treatment modality pharmacy. Password – a private identification that is created by a user to obtain access to an electronic drug record keeping system.

Personal Identifier – a unique user name or number for identifying and tracking a specific user's access to an electronic drug record keeping system such as Social Security number, user identification number, or employee number

Positive Identification -

- 1. has the same meaning as defined in Section 1119 of this Part, except that a specific hospital having a closed electronic drug record keeping system may be permitted to use identifiers utilizing both a password combined with a personal identifier to document the positive identification of each user for the prescribing and administration of a drug, provided the pharmacist-in-charge has determined:
  - a. adequate audit controls are in place to detect and deter drug diversion;
  - b. adequate access controls are in place to assure the identity of the user and to assign accountability of the user for any drug transaction;
  - c. adequate safeguards are in place to prevent and detect the unauthorized use of an individual's password and personal identifier;
  - d. an ongoing quality assurance program is in place to ensure that all three provisions cited above in this definition are being fulfilled and reviewed; and
  - e. appropriate policies and procedures are in place to address all four provisions cited above in this definition.
- 2. All of the above notwithstanding, however, positive identification as defined in Section 1119 of this Part shall always be used to document the:
  - a. dispensing, compounding, or prepackaging of a drug;
  - b. removal and possession of a controlled substance to administer to a patient; and
  - c. waste of a controlled substance.

*Provider Pharmacy* – a hospital pharmacy which provides administrative control, staffing as well as products and services to a hospital off-site satellite pharmacy.

Registered Patient – A person receiving health care services within a hospital facility, or an animal receiving veterinary care within a veterinary teaching hospital owned or operated by a public university in this state.

Unit Dose – the packaging of individual prescription doses in a suitable container that have been properly labeled as to the identity of the generic, chemical, or trade name of the drug; strength; lot number; and expiration date. All unit doses qualify as "prepackaging" as used in this Chapter. However, all prepackaging is not necessarily in unit dose packaging.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, LR 33:1132 (June 2007), LR 39:1282 (May 2013), LR 40:2256 (November 2014), effective January 1, 2015, LR 41:2147 (October 2015), amended by the Department of Health, Board of Pharmacy, LR 46:582 (April 2020), amended LR 46:973 (June 2020).

#### §1505. Hospital Pharmacy Permit

A. A hospital pharmacy permit shall be required to operate a pharmacy department located within a hospital for registered patients in a hospital. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of this Part.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, LR 33:1132 (June 2007), amended by the Department of Health, Board of Pharmacy, LR 46:583 (April 2020).

# §1509. Drug Distribution Control

- A. The hospital pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, distribution, control, accountability, and patient administration and management of drugs. The staff of the hospital pharmacy shall cooperate with the pharmacist-in-charge in meeting drug control requirements in ordering, administering, and accounting for pharmaceuticals.
  - 1. Procedure Manual. The pharmacist-in-charge shall maintain written procedures for the safe and efficient distribution of pharmaceutical products and delivery of pharmacy care. An updated copy shall be available for board inspection upon request.
  - 2. Inventories. The pharmacist-in-charge shall:
    - a. perform an annual inventory on all controlled dangerous substances; and
    - b. maintain a perpetual inventory of Schedule I and II controlled dangerous substances.
  - 3. Records. The pharmacist-in-charge shall be responsible for maintaining the following records:
    - a. a record of all drugs procured, the quantity received, and the name, address and wholesale distributor license number of the person from whom the drugs were procured.
    - b. all drug orders and records relating to the practice of pharmacy.
      - i. Records of drugs dispensed shall include, but are not limited to:
        - (a) the name, strength, and quantity of drugs dispensed;
        - (b) the date of dispensing;
        - (c) the name of the hospital patient to whom, or for whose use, the drug was dispensed; and
        - (d) positive identification of all pharmacists involved in the dispensing.
      - ii. All other records relating to the practice of pharmacy other than dispensing shall include, but are not limited to:
        - (a) the name of the hospital patient to whom, or for whose benefit, the activity was performed.
        - (b) the nature of the pharmacy practice activity performed.
        - (c) the results of the activity, if applicable; and
        - (d) positive identification of all pharmacists involved in the activity, identifying the function performed by each pharmacist.
      - iii. Records of drugs dispensed to patients for use outside the hospital shall be maintained in compliance with Section 1123 of this Part.
    - c. a record of all drugs compounded or prepackaged for use only within that hospital, which shall include at least the following:
      - i. name of drug, strength, quantity, and dosage form;
      - ii. manufacturer's or distributor's control number (except for patient-specific sterile compounded preparations);
      - iii. manufacturer's or distributor's name, if a generic drug is used;
      - iv. pharmacy control number;
      - v. manufacturer's distributor's expiration date (except for patient-specific sterile compounded preparations);
      - vi. pharmacy's expiration date or beyond-use date;
      - vii. identification of the licensed person responsible for the compounding or prepackaging of the drug.
    - d. a record of the distribution of drugs to patient care areas and other areas of the hospital held for administration, which shall include at least the following:

- i. the name, strength, dosage form, and amount of the drug distributed;
- ii. the area receiving the drug;
- iii. the date distributed;
- iv. identification of the individual receiving the drug if it is a controlled dangerous substance;
- v. the area of the hospital receiving the controlled dangerous substance shall make a record of all such drugs administered to patients. Such records shall include at least the following:
  - (a) name of the patient;
  - (b) name, dosage form, and strength when applicable of the drug;
  - (c) date and time the drug was administered;
  - (d) quantity administered.
  - (e) positive identification of the personnel administering the drug.
- e. a log that shall be maintained of all changes made to a drug record in an electronic drug recordkeeping system after a drug transaction has been made. The log shall contain at least, but is not limited, to the following:
  - i. date and time of change;
  - ii. changes made;
  - iii. person making the change.
- B. Automated Medication Systems. A hospital pharmacy may use one or more automated medication systems in compliance with the provisions of Chapter 12 of this Part.
  - 1. When the pharmacy uses an electronic product verification process as described in Section 1217 of this Part, and in the absence of any subsequent human intervention in the automated drug product selection process, the pharmacist-in-charge may elect to forego manual checks of drug products selected in that manner, provided however, that such selection by the pharmacist-in-charge shall require an initial quality assurance validation followed by an ongoing quality review at intervals no greater than 90 days since the previous review, all conducted by a pharmacist.
  - 2. The pharmacist-in-charge remains accountable to the board for the accuracy of all drug distribution activities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004, amended LR 40:2257 (November 2014), effective January 1, 2015, LR 41:1488 (August 2015), amended by the Department of Health, Board of Pharmacy, LR 46:583 (April 2020).

#### §1511. Prescription Drug Orders

A. The pharmacist shall review the practitioner's medical order prior to dispensing the initial dose of medication, except in cases of emergency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004.

## §1512. Hospital Pharmacy Prepackaging

- A. Prepackaging is the preparation of medication in a unit-of-use container by credentialed pharmacy personnel in a pharmacy prior to the receipt of a prescription or medical order for ultimate issuance by a pharmacist in Louisiana.
- B. Labeling. The label on the prepackaged container shall contain the following minimum information:
  - 1. drug name;
  - 2. dosage form;
  - 3. strength;
  - 4. quantity dispensed when appropriate;
  - 5. special storage requirements;
  - 6. a unique pharmacy prepackage lot number which shall correspond to the following:
    - a. name of manufacturer and/or distributor;
    - b. manufacturer's lot or batch number;
    - c. date of preparation; and
    - d. verifying pharmacist's initials.
  - 7. expiration date, according to United States Pharmacopeia (USP) guidelines.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

#### §1513. Labeling

A. All drugs dispensed or compounded by a hospital pharmacy, intended for use within the facility, shall be dispensed in appropriate containers and adequately labeled as to identify patient name and location, drug name(s) and strength, and medication dose(s). Additionally, compounded preparations and sterile preparations shall be labeled with the expiration date or beyond-use date, initials of the preparer, and the pharmacist performing the final check.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, LR 38:1235 (May 2012).

#### §1515. Ambulance Service Drugs

A. Hospital pharmacies that supply prescription drugs, including any controlled dangerous substances, to any authorized ambulance service or emergency medical service shall maintain proper records to ensure control, proper utilization, inventory, and accountability.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004.

# §1517. Pharmacist Absence/Drug Cabinet

- A. Pharmacist Absence. In the absence of a licensed pharmacist, admittance to the pharmacy by unauthorized persons is prohibited. When the pharmacy is closed, a pharmacist shall be on emergency call.
  - 1. Within a veterinary teaching hospital owned or operated by a public university in this state, the pharmacist-in-charge shall approve policies and procedures detailing the person(s) authorized to access the pharmacy after-hours.
- B. Drug Cabinets. In the absence of a licensed pharmacist, arrangements shall have been formulated in advance by the pharmacist-in-charge to provide drugs for the patients by the use of drug cabinets.
  - 1. Emergency Use. A drug cabinet is solely intended for the proper and safe storage of needed drugs when the pharmacy is closed and shall be available for emergency use by authorized hospital personnel only.
  - 2. Security. The drug cabinet shall be a securely constructed and locked enclosure located outside the permitted pharmacy ensuring access to authorized personnel only.
  - 3. Inventory. The pharmacist-in-charge shall be responsible for the selection and quantity of the drugs to be maintained in the drug cabinet and shall maintain a perpetual inventory of any controlled dangerous substances stored in the drug cabinet.
  - 4. Labeling. Medications stored in a drug cabinet shall be properly labeled.
  - 5. Quantities. Prepackaged drugs shall be available in amounts sufficient for immediate therapeutic or emergency requirements.
  - 6. Accessibility. Written medical practitioner's orders and proof of use, if applicable, shall be provided when a drug cabinet inventory is utilized.
  - 7. Inspection. Medications stored in a drug cabinet shall be inspected every 30 days.
  - 8. Policy Manual. A policy and procedure manual shall be maintained to implement the drug cabinet requirements and is to be made available to the board upon request for inspection and approval.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2093 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:587 (April 2020).

#### §1519. Drug Returns; Drug Disposal

- A. In a hospital with a permitted hospital pharmacy on site, drugs may be returned to the pharmacy for redispensing in accordance with good professional practice standards.
- B. When a patient or his designee wishes to return previously dispensed prescription drugs to a pharmacy for disposal, the pharmacy shall inform the patient or his designee of the disposal mechanisms available to him. In the event the pharmacy elects to accept such previously dispensed products for disposal, the pharmacy shall comply with the following requirements:

- 1. From the time of receipt of such products until the time of disposal, the pharmacy shall quarantine such products to keep them separate from its active dispensing stock and shall take appropriate security measures to prevent the theft or diversion of such products.
- 2. The pharmacy shall comply with the provisions of <u>21 CFR §1317</u> or its successor for the pharmacy's disposal of controlled substances and other non-hazardous waste pharmaceuticals.
- 3. The pharmacy shall comply with the provisions of 40 CFR §261 or its successor for the pharmacy's disposal of hazardous waste pharmaceuticals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:793 (June 2020).

#### §1521. Off-Site Pharmacy Services

- A. Availability. Pharmacy services may be procured contractually from outside the hospital for inpatient administration.
- B. Contractual agreements shall provide for:
  - 1. emergency the pharmacy provider shall be available for on-call for emergency pharmacy services;
  - 2. storage adequate drug storage facilities shall be provided to the pharmacy provider;
  - 3. labeling prescription drugs supplied to hospital inpatients shall be properly labeled to ensure that adequate control, supervision, and recall of medication are monitored;
  - 4. contractual pharmacy service off-site contractual pharmacy services rendered to the hospital shall be in accordance with federal and state laws, rules, and regulations.
- C. A pharmacy providing off-site contractual pharmacy services to a hospital shall not be considered a hospital pharmacy.
- D. Medications. Prescription medications independently supplied to registered patients shall comply with all appropriate board regulations and statutes and/or hospital rules, regulations, and policies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004.

# §1523. Outpatient Pharmacy Dispensing

- A. Hospital outpatient dispensing shall require a separate pharmacy permit for the specialty classification(s) under these regulations. All records including the annual inventory of controlled dangerous substances for the outpatient pharmacy shall be maintained and kept separate and apart from that of the inpatient pharmacy, as the outpatient pharmacy may not acquire drugs through the hospital pharmacy permit under the provisions of the Robinson-Patman Act, 15 USC §13(c).
- B. Nothing in this Section shall prohibit the dispensing of certain prescriptions from the hospital pharmacy, as allowed under the Robinson-Patman Act, 15 USC §13(c), including:
  - 1. dispensing to the hospital inpatient for use in his treatment at the hospital;
  - 2. dispensing to the patient admitted to the hospital's emergency facility for use in the patient's treatment at that location;
  - 3. dispensing to the hospital outpatient for personal use on the hospital premises;
  - 4. dispensing in the context of a genuine take-home prescription, intended for a limited and reasonable time as a continuation of, or supplement to, the treatment that was administered at the hospital to the recipient while an inpatient, an outpatient, or an emergency facility patient if the patient needs that treatment; or
  - 5. dispensing to the hospital's physicians, employees, or its students for their personal use or for the personal use of their dependents.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2094 (October 2003), effective January 1, 2004.

#### §1525. Hospital Off-Site Satellite Pharmacy

- A. Issuance and Maintenance of Permit
  - 1. A hospital pharmacy may establish a hospital off-site satellite pharmacy within a facility bearing the same hospital license number as the facility housing the provider pharmacy.
  - 2. The provider pharmacy, acting through its pharmacist-in-charge, shall make application for the satellite pharmacy permit using a form and process specified by the board.

- 3. The applicant shall pay the fee for the initial issuance and renewal as specified in R.S. 37:1184<sup>1</sup>.
- 4. Once issued, the satellite pharmacy permit shall expire at midnight on December 31 of each year, unless suspended or revoked earlier by the board.
- 5. The satellite pharmacy shall renew its permit using the form and process specified by the board.
- 6. The operation of a hospital off-site satellite pharmacy without a pharmacy permit, or with an expired permit, shall constitute a violation of R.S. 37:1241(A)(12).
- 7. In the event a provider pharmacy sustains a change of ownership sufficient to require a new pharmacy permit, the hospital off-site satellite pharmacy shall also obtain a new pharmacy permit.
- 8. In the event a provider pharmacy closes permanently and surrenders its permit, the hospital off-site satellite pharmacy shall also close and surrender its permit.

#### B. General Requirements

- 1. The hospital off-site satellite pharmacy shall be of sufficient size and shall contain sufficient fixtures, equipment and supplies commensurate with the scope of practice for that pharmacy, provided:
  - a. the pharmacy shall be of sufficient size to allow for the safe and proper storage of prescription drugs and/or controlled substances;
  - b. all areas where drugs and devices are stored shall be dry, well-lighted, well ventilated, and maintained in a clean and orderly condition, and more specifically, storage areas shall be maintained at temperatures which will ensure the integrity of drugs prior to their dispensing as stipulated by the United States Pharmacopeia (USP) and/or the manufacturer's or distributor's product labeling unless otherwise indicated by the board;
  - c. the pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time when the pharmacist is not present; and
  - d. prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information.
- 2. The pharmacist-in-charge of the provider pharmacy shall be responsible for all pharmacy operations involving the hospital off-site satellite pharmacy including supervision of pharmacy personnel.
- 3. The hospital off-site satellite pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times the hospital off-site satellite pharmacy is open for the transaction of business.
- 4. The hospital off-site satellite pharmacy shall have a sufficient number of pharmacists on duty to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.
- 5. When the hospital off-site satellite pharmacy is closed or there is no pharmacist on duty, other individuals shall not have access to the hospital off-site satellite pharmacy except for temporary absences as provided for in Chapter 11 of this Part.
- 6. The provider pharmacy and the hospital off-site satellite pharmacy shall have:
  - a. the same owner; and
  - b. share a common electronic file or have the appropriate technology to allow access to sufficient information necessary or required to process a prescription or medical order.
- 7. The hospital off-site satellite pharmacy shall comply with the recordkeeping provisions identified in Chapter 11 of this Part.
- 8. The compounding of preparations in a hospital off-site satellite pharmacy shall be accomplished in compliance with the current federal standards applicable to such practices: USP Chapter 797, or its successor, for the compounding of sterile preparations, and USP Chapter 795, or its successor, for the compounding of non-sterile preparations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:1283 (May 2013), amended by the Department of Health, Board of Pharmacy, LR 46:583 (April 2020).

#### §1529. Investigational Drugs

A. Where the hospital pharmacy is a participant in one or more investigational drug studies, the pharmacy may dispense investigational drug products as well as commercially available drug products to patients enrolled in a study, whether or not the patient is a registered patient of the hospital.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 46:575 (April 2020).

#### [End of Chapter 15]

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Note:

1 The statutory list of fees in R.S. 37:1184 is no longer current. The current list of fees is found in Chapter 1 of the administrative code, more specifically in Section 115. The board has not yet revised Section 1525 to remove the obsolete citation.

# **Chapter 17. Institutional Pharmacy**

#### Subchapter A. General Requirements

# §1701. Cross References

A. For all regulations that apply to permitted institutional pharmacies concerning pharmacy practices and records not specifically stated in this Chapter, refer to Chapter 11 of this Part.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2094 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:583 (April 2020).

# §1703. Definitions

- A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this section: *Institutional Facility* 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(n):
  - a. convalescent home;
  - b. nursing home;
  - c. extended care facility;
  - d. mental health facility;
  - e. rehabilitation center;
  - f. psychiatric center;
  - g. developmental disability center;
  - h. drug abuse treatment center;
  - i. family planning clinic;
  - j. penal institution;
  - k. hospice;
  - l. public health facility;
  - m. athletic facility.

*Institutional Pharmacy* – that physical portion of an *institutional facility* where drugs, devices, and other materials used in the diagnosis and treatment of an 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.

Long Term Care Facility – a nursing home, retirement center, 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2094 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:583 (April 2020).

#### §1705. Institutional Pharmacy Permit

- A. An institutional pharmacy permit shall be required to operate a pharmacy department located within an institutional facility, other than a hospital or penal institution, for residents or patients of that institutional facility. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of this Part
- B. Pharmacies operated within a hospital shall be operated in accordance with Chapter 15 of this Part.
- C. Pharmacies operated within a correctional center shall be operated in accordance with Chapter 18 of this Part.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2095 (October 2003), effective January 1, 2004, LR 39:313 (February 2013), amended by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

# §1707. Drug Cabinet

- A. In the absence of a licensed pharmacist, arrangements shall have been formulated in advance by the pharmacist-in-charge to provide drugs for the residents/patients by the use of drug cabinets. When the pharmacy is closed, a pharmacist shall be on emergency call.
  - 1. Emergency Use. A drug cabinet is solely intended for the proper and safe storage of needed drugs when the pharmacy is closed and shall be available for emergency use by authorized facility personnel only.
  - 2. Security. The drug cabinet shall be a securely constructed and locked enclosure located outside the permitted pharmacy area ensuring access by authorized personnel only.
  - 3. Inventory. The pharmacist-in-charge shall be responsible for the selection and quantity of drugs to be maintained in the drug cabinet and shall maintain a perpetual inventory of any controlled dangerous substances. Medications shall be available in quantities sufficient only for immediate therapeutic needs.
  - 4. Labeling. Medications stored in a drug cabinet shall bear a label with the following minimum information:
    - a. drug name;
    - b. dosage form;
    - c. strength;
    - d. name of manufacturer and/or distributor;
    - e. manufacturer's lot or batch number;
    - f. pharmacist's initials; and
    - g. expiration date, according to United States Pharmacopeia guidelines.
  - 5. Accountability. Documented medical practitioner's orders and proof of use shall be provided when any of the drug cabinet inventory is utilized.
  - 6. Inspection. The pharmacy shall inspect medications stored in a drug cabinet every 30 days, plus or minus five days.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007).

# Subchapter B. Emergency Drug Kits

# §1709. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section: *Emergency Drug Kit (EDK)* – for long-term care facilities or other board-approved sites, other than a hospital, means a drug kit containing designated *emergency drugs* which may be required to meet the immediate therapeutic needs of a resident or patient.

*Emergency Drugs* – those drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients or residents because of delay resulting from obtaining such medications from such other source.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095 (October 2003), effective January 1, 2004.

# §1711. Emergency Drug Kit Permit

- A. A long-term care facility, institutional facility without an institutional pharmacy, or other board-approved site, other than a hospital, that desires to maintain an Emergency Drug Kit shall obtain an EDK permit from the board.
- B. Permit Application and Requirements. Application for an EDK permit shall be made on a form provided by the board.
  - 1. The provider pharmacy shall apply to the board for an EDK permit. The administrator of the applicant facility shall also sign the application for said permit. Upon compliance with the required provisions, the provider pharmacy shall be issued a permit by the board for the provider pharmacy to establish and maintain an EDK in the facility.
  - 2. The provider pharmacy shall be a Louisiana-licensed pharmacy.
  - 3. Only one provider pharmacy shall be assigned to and be responsible for each EDK.
  - 4. EDK permits are institutional facility-specific and not transferable.
  - 5. A separate permit is required for each EDK.

- 6. The original EDK permit shall be readily retrievable at the provider pharmacy. A copy of the EDK permit shall be maintained in the room where the EDK is located.
- C. Pharmacist-in-Charge. The pharmacist-in-charge of the provider pharmacy shall be the pharmacist-in-charge of the EDK. The maintenance of the EDK shall at all times remain the responsibility of the pharmacist-in-charge.
- D. Renewal. Each EDK permit issued by the board shall be renewed annually by the provider pharmacy, at the time designated by the board. If an EDK permit is not renewed by July 1 of each year, the existing permit shall expire and become null and void.
- E. Cancellation Prior to Renewal. In the event the facility or provider pharmacy elects to cancel the permit prior to the renewal date, the pharmacy shall relinquish the permit to the board office no later than 10 days following the date of cancellation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2095 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

#### §1713. Emergency Drug Kit Requirements

- A. Emergency Use. An EDK is solely intended for the immediate therapeutic emergency needs of a resident or patient.
- B. Security. The EDK shall be tamper-evident and shall be maintained in a secure enclosure located within the institutional facility and shall be available for emergency use by authorized personnel only.
- C. Exterior Identification and Labeling. The EDK shall be clearly labeled to indicate that it is an emergency drug kit. In addition, the attached exterior label shall have an inventory of contents and contact information of the provider pharmacy.
- D. Labeling. Medications stored in an EDK shall bear a label with the following minimum information:
  - 1. drug name;
  - 2. dosage form;
  - 3. strength;
  - 4. name of manufacturer and/or distributor;
  - 5. manufacturer's lot or batch number; and
  - 6. expiration date, according to United States Pharmacopeia guidelines.
- E. Storage. All drugs in an EDK shall be stored to ensure a proper environment for the preservation of the drugs. If federal or state laws or regulations require adequate storage outside the EDK, documentation shall be kept with the EDK properly identifying this special storage requirement and drug(s) involved.
- F. Policies and Procedures. Policies and procedures shall be maintained by the provider pharmacy and the applicant facility to implement the EDK requirements.
- G. Accountability. Documented medical practitioner's orders and proof of use shall be provided when an EDK inventory is utilized. Medication administered to patients from the EDK shall be documented with the following information, in accordance with the institutional facility policy manual, that shall be immediately reduced to writing and a copy delivered to the provider pharmacy:
  - 1. name of the resident patient;
  - 2. drug name, strength, and quantity;
  - 3. nature of the emergency;
  - 4. time and date of administration;
  - 5. name of person administering the medication; and
  - 6. name of prescriber authorizing the medication.
- H. Records. Records shall be readily retrievable and comply with applicable federal and state laws and regulations.
- I. Inspection.
  - 1. The provider pharmacy shall inspect the EDK every 30 days, plus or minus five days. Proper documentation of these inspections, EDK inventory, and all records of use shall be maintained and made available to the board upon request.
  - 2. The EDK shall be available for inspection by the board.
- J. The placement of controlled dangerous substances in an EDK in non-federally registered long-term care facilities shall be deemed in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970 provided that:
  - 1. controlled dangerous substances shall be stored in the EDK as deemed necessary and jointly approved by the pharmacist, medical director and the director of nursing services;

- 2. the source from which the controlled dangerous substances for EDKs are obtained shall be a pharmacy licensed by the board in possession of a valid DEA registration and Louisiana CDS license;
- 3. the number of different controlled dangerous substances in a single EDK shall be limited to a maximum of eight separate drug entities with not more than eight single-use containers of each drug entity;
- 4. the EDK containing controlled dangerous substances shall be closed with a tamper proof seal and kept in a locked medication room, cart or closet;
- 5. access to controlled dangerous substances stored in an EDK shall be limited to the pharmacist, a practitioner, the director of nursing services, or the registered nurse or licensed practical nurse on duty;
- 6. controlled dangerous substances stored in an EDK shall be administered to a patient only by authorized personnel and only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 CFR 1306.11 and 21 CFR 1306.21 or their successors;
- 7. a usage record shall be retained in the EDK for each separate drug included which shall be completed by the nursing staff when retrieving any controlled dangerous substance(s) from the EDK;
- the pharmacist at the provider pharmacy shall receive and retain all completed usage records for a minimum of two years;
- 9. when the EDK is opened:
  - a. the pharmacist shall be notified by the facility within 24 hours; and
  - b. shift counts shall be performed by the nursing staff on all controlled dangerous substances until the kit is resealed by the pharmacist.
- 10. shift counts of the controlled dangerous substances contained in the EDK shall not be required when the EDK is sealed;
- 11. the pharmacist shall check the controlled dangerous substances in the EDK at least monthly and so document that check inside the kit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004, amended LR 39:312 (February 2013), amended by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

# **Subchapter C. Drug Abuse Treatment Center Pharmacies**

# §1715. Purpose

A. The board may issue a pharmacy permit for a drug abuse treatment center operating in the state of Louisiana where drugs are dispensed and pharmacy primary care is provided.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004.

#### §1717. Cross References

A. For all regulations that apply to drug abuse treatment center pharmacies concerning pharmacy practices not specifically stated in this Subchapter, refer to Chapter 11 of this Part.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

# §1719. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section: *Administer or Administration* – the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

Authorized Personnel – individuals who, within the scope of their authority granted by mutual agreement of the drug abuse treatment center's pharmacist-in-charge and director, are granted access to the drug abuse treatment center's pharmacy department as part of his duties.

Dispense or Dispensing – 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.

Drug Abuse Treatment Center – any establishment, facility, or institution, public or private, whether operated for profit or not, which primarily offers, or purports to offer, maintain, or operate facilities for the residential or outpatient diagnosis, care, treatment, or rehabilitation of two or more non-related individuals, who are patients as defined herein, excluding, however, any hospital or mental hospital otherwise licensed by the Department of Health. Patient or Client – a person who is dependent on, or otherwise suffering physically or mentally from the use of, or abuse of, controlled dangerous substances and who requires continuing care of a drug abuse treatment center. Perpetual Inventory – a computer record of inventory kept continuously up to date by detailed entries of all incoming and outgoing items. This includes inventory on hand, purchases, and dispensing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2096 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

#### §1721. Drug Abuse Treatment Center Pharmacy Permit

A. A drug abuse treatment center pharmacy permit shall be required to operate a pharmacy department located within a drug abuse treatment facility for patients of that facility. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of this Part.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

# §1723. Minimum Security Controls for Drug Abuse Treatment Centers

- A. Persons enrolled in a drug abuse treatment center shall wait for their prescriptions in an area physically separated from the controlled dangerous substance (CDS) storage and dispensing area. This requirement shall be enforced by the drug abuse treatment center physician(s), pharmacist(s), and employees.
- B. All CDS used in a drug abuse treatment center shall be securely locked and accessible to authorized personnel within that facility only.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097 (October 2003), effective January 1, 2004.

# §1725. Records and Reports of Drug Abuse Treatment Centers

- A. All persons licensed by the Department of Health to operate a drug abuse treatment center and who possess a Drug Enforcement Administration (DEA) registration to purchase, possess, and use CDS shall keep the following records:
  - 1. records of CDS received by approved persons, including date of receipt, name and address of distributor, type and quantity of such drugs received, and the signature of the individual receiving the CDS. A duplicate invoice or separate itemized list furnished by the distributor will be sufficient to satisfy this record requirement, provided it includes all required information and is maintained in a separate file. In addition, duplicate copies of federal order forms for CDS listed in Schedule II must be retained; and
  - 2. records of CDS administered or dispensed, including date of administration or dispensing, name of patient, signature of person administering or dispensing, type and quantity of drug, and such other information as may be required by state and federal laws and regulations.
- B. Records of perpetual inventories shall be kept at the permitted site as prescribed by law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2097 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

[End of Chapter 17]

# **Chapter 18. Correctional Center Pharmacy**

# §1801. Correctional Center Pharmacy Permit

- A. A correctional center pharmacy permit shall be required to operate a pharmacy located within a correctional center owned and/or operated by the Louisiana Department of Public Safety and Corrections, or its successor, (hereinafter, "the department"), or a local law enforcement agency, to provide medications and pharmacy care for offenders residing in that correctional center or another correctional center owned and operated by the department or local law enforcement agency. The pharmacy in the correctional center may also provide medications and pharmacy care to offenders assigned to that facility and residing at home or another housing location.
- B. In the event a pharmacy located within the state but outside a correctional center intends to provide medications and pharmacy care on a contractual basis to offenders residing in, or assigned to, a correctional center owned and/or operated by the department or local law enforcement agency that pharmacy shall first obtain a correctional center pharmacy permit.
- C. In the event a nonresident pharmacy intends to provide medications and pharmacy care on a contractual basis to offenders residing in, or assigned to, a correctional center owned and/or operated by the department or local law enforcement agency or to any offender in the custody of the department or local law enforcement agency shall first obtain a nonresident correctional center pharmacy permit, and further, shall comply with the provisions of this Chapter with the exception of acquiring a separate correctional center pharmacy permit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1236 (May 2012), amended LR 39:3074 (November 2013), amended by the Department of Health, Board of Pharmacy, LR 46:571 (April 2020).

#### §1803. Permit Application Procedures

- A. Application for Initial Issuance of Permit
  - 1. The applicant for a correctional center pharmacy permit shall complete the application form supplied by the board and submit it with the required attachments and appropriate fees, as set forth in R.S. 37:1184<sup>1</sup>, to the board.
  - 2. Once received by the board, an application for the permit shall expire one year thereafter. Fees attached to an expired application shall be forfeited by the applicant and deposited by the board.
  - 3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
  - 4. The applicant may be required to personally appear before the board or one of its committees prior to any decision on the permit application.
  - 5. The applicant shall be required to submit to the criminal history record check process used by the board, unless waived by the board.
- B. Application for Renewal of Permit
  - 1. Without respect to the date of initial issuance, a correctional center pharmacy permit shall expire at midnight on December 31 of every year, unless surrendered, suspended, or revoked sooner in accordance with the <a href="Pharmacy Practice Act">Pharmacy Practice Act</a> or this Part.
  - 2. A correctional center pharmacy shall not operate with an expired permit.
  - 3. The pharmacy shall complete the renewal application form supplied by the board and submit it with any required attachments and appropriate fees on or before the expiration date.
  - 4. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
- C. Application for Reinstatement of Expired Permit
  - 1. The applicant shall complete an application form for this specific purpose supplied by the board and submit it with any required attachments and appropriate fees to the board.
  - 2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
  - 3. An application for the reinstatement of a permit which has been expired:
    - a. less than one year may be approved by the board's administrative personnel;
    - b. more than one year but less than five years may be approved by a member of the board charged with such duties:
    - c. more than five years may only be approved by the full board following a hearing to determine whether the applicant is competent to operate the pharmacy and whether the reinstatement is in the public's best interest.

- 4. Applications requiring a reinstatement hearing shall be accompanied by payment of the administrative hearing fee authorized by R.S. 37:1184<sup>1</sup>.
- D. Application for Reinstatement of Suspended or Revoked Permit
  - 1. The applicant shall complete an application form for this specific purpose supplied by the board and submit it with any required attachments and appropriate fees to the board.
  - 2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
  - 3. The application may only be approved by the full board following a hearing to determine whether the applicant is competent to operate the pharmacy and whether the reinstatement is in the public's best interest.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1236 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:572 (April 2020).

### §1805. Maintenance of Permit

- A. A correctional center pharmacy permit is valid only for the entity to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a permit be valid for any premises other than the business location for which it is issued.
- B. The owner of the pharmacy shall appoint a Louisiana-licensed pharmacist as the pharmacist-in-charge of the permit. The owner of the pharmacy and the pharmacist-in-charge shall comply with the provisions of Section 1105 of this Part.
- C. A pharmacy contemplating permanent closure of its prescription department shall comply with the provisions of Section 1133 of this Part.
- D. A pharmacy contemplating a change in ownership shall comply with the provisions of Section 1135 of this Part.
- E. A pharmacy contemplating a change in location shall comply with the provisions of Section 1137 of this Part.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1236 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:572 (April 2020).

# §1807. Prescription Department Requirements

- A. The prescription department of a correctional center pharmacy shall comply with the minimum specifications identified in Section 1103 of this Part, and further, the specifications provided for the correctional center pharmacy permit may not be held or used by any other pharmacy permit.
- B. To ensure adequate access to medications and pharmacy care, the prescription department of a correctional center pharmacy shall be open for business a minimum of 10 hours per week, with said business hours posted at the pharmacy entrance.
- C. A pharmacist shall be on duty at all times during regular operating hours of the pharmacy. When the pharmacy is closed, a pharmacist shall be available for emergency calls.
- D. In the absence of a pharmacist, there shall be no access to the prescription department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 (May 2012), amended LR 39:3074 (November 2013), amended by the Department of Health, Board of Pharmacy, LR 46:572 (April 2020).

### §1809. Drug Distribution Control

- A. The pharmacist-in-charge shall be responsible for the safe and efficient procurement, receipt, storage, distribution, control, accountability, and patient administration and management of all drugs used in the correctional center. The administration and staff of the facility shall cooperate with the pharmacist-in-charge in meeting drug control requirements in ordering and accounting for drugs.
  - 1. The pharmacist-in-charge shall maintain a written policy and procedure manual for the safe and efficient distribution of drug products and delivery of pharmacy care. A copy of the current version of the manual shall be available for board inspection upon request.
  - 2. The pharmacist-in-charge shall be responsible for making and keeping pharmacy records in compliance with the provisions of Sections 1119 through 1129 of this Part.
  - 3. The procurement, storage, security, and recordkeeping of controlled substances shall be in compliance with the provisions of Chapter 27 of this Part.

- B. The pharmacy may utilize automated medication systems, but only in compliance with Chapter 12 of this Part.
- C. The pharmacy located within a correctional center may utilize drug cabinets located outside the prescription department of that facility to provide access to a limited inventory of medications when the prescription department is closed.
  - 1. A drug cabinet is intended solely for the proper and safe storage of needed drugs when the pharmacy is closed, and such drugs shall be available for emergency use only by authorized facility personnel.
  - 2. The drug cabinet shall be a securely constructed and locked enclosure located outside the prescription department ensuring access by authorized personnel only.
  - 3. The pharmacist-in-charge shall be responsible for the selection and quantity of drugs to be maintained in the drug cabinet and shall maintain a perpetual inventory of any controlled dangerous substances stored therein. Medications shall be available in quantities sufficient only for immediate therapeutic needs.
  - 4. Medications stored in a drug cabinet shall bear a legible label with the following minimum information:
    - a. drug name, strength, and dosage form;
    - b. name of manufacturer or distributor and their lot or batch number;
    - c. expiration date, in compliance with the relevant standards from the United States Pharmacopeia (USP);
    - d. for prepackaged medications, the pharmacy's lot number and initials of the pharmacist.
  - 5. Documented orders from the medical practitioner and proof of use records shall be provided when any medications are removed from the drug cabinet.
  - 6. The pharmacy shall inspect medications stored in a drug cabinet on a periodic basis, but no more than thirty days since the previous inspection.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:572 (April 2020).

# §1811. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section: *Emergency Drug Kit (EDK)* – a container holding designated *emergency drugs* which may be required to meet the immediate therapeutic needs of an offender.

*Emergency Drugs* – those drugs which may be required to meet the immediate therapeutic needs of an offender and which are not available from any other authorized source in sufficient time to prevent risk of harm to the offender because of a delay resulting from obtaining such medications from such other source.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:572 (April 2020).

#### §1813. Emergency Drug Kit Permit

- A. A correctional center pharmacy located outside a correctional center intending to use one or more emergency drug kits within the correctional center shall first obtain an EDK permit from the board.
- B. Application for Initial Issuance of Permit
  - 1. The correctional center pharmacy shall apply to the board for the permit.
  - 2. The applicant shall complete the application form supplied by the board and submit it with the required attachments and appropriate fees, as set forth in R.S. 37:1184<sup>1</sup>, to the board.
  - 3. Once received by the board, an application for the permit shall expire one year thereafter. Fees attached to an expired application shall be forfeited by the applicant and deposited by the board.
  - 4. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
- C. Application for Renewal of Permit
  - 1. Without respect to the date of initial issuance, an EDK permit shall expire at midnight on June 30 of every year, unless relinquished, surrendered, suspended, or revoked sooner in accordance with the Pharmacy Practice Act or this Part.
  - 2. An EDK shall not be maintained or used with an expired permit.
  - 3. The correctional center pharmacy shall complete the renewal application form supplied by the board and submit it with any required attachments and appropriate fees on or before the expiration date.
  - 4. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.

- D. Application for Reinstatement of Expired Permit
  - 1. The applicant shall complete an application form for this specific purpose supplied by the board and submit it with any required attachments and appropriate fees to the board.
  - 2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
  - 3. An application for the reinstatement of an EDK permit which has been expired:
    - a. less than one year may be approved by the board's administrative personnel;
    - b. more than one year but less than five years may be approved by a member of the board charged with such duties;
    - c. more than five years may only be approved by the full board following a hearing to determine whether the reinstatement of the permit is in the public's best interest.
  - 4. Applications requiring a reinstatement hearing shall be accompanied by payment of the administrative hearing fee authorized by R.S. 37:1184<sup>1</sup>.

#### E. Maintenance of Permit

- 1. EDK permits are specific to a correctional center and a correctional center pharmacy and they are not transferable.
- 2. In the event multiple kits are required for a correctional center, a separate permit shall be required for each EDK.
- 3. The original EDK permit shall be displayed in the correctional center pharmacy supplying the EDK, and a copy of the permit shall be maintained in the room or area where the EDK is located.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1237 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:573 (April 2020).

#### §1815. Emergency Drug Kit Requirements

- A. The EDK shall be tamper-evident, shall be maintained in a secure enclosure located within the correctional center, and shall be available for emergency use by authorized personnel only.
- B. The EDK shall be clearly labeled to indicate it is an emergency drug kit, and further, the attached exterior label shall identify the inventory of contents as well as contact information for the correctional center pharmacy responsible for maintaining the kit.
- C. Medications stored in an EDK shall bear a label with the following minimum information:
  - 1. drug name;
  - 2. dosage form;
  - 3. drug strength;
  - 4. name of manufacturer and/or distributor;
  - 5. manufacturer's lot or batch number; and
  - 6. expiration date, according to relevant standards from the United States Pharmacopeia (USP).
- D. The EDK shall be stored in a proper environment for the preservation of the drugs contained therein, in compliance with the relevant USP standards. In the event federal or state laws or rules require storage outside the EDK for one or more drugs in the EDK, documentation shall be maintained with the EDK properly identifying this special storage requirement and the drug(s) affected.
- E. The correctional center and correctional center pharmacy shall maintain policies and procedures to implement and maintain these requirements. These policies and procedures may be maintained in written or electronic format and shall be available for review by the board or its agents.
- F. When an authorized prescriber issues an order for the administration of a drug contained within the EDK, the order and proof of use shall be delivered in written or electronic format to the correctional center pharmacy; further, such records shall contain the following minimum information:
  - 1. name of offender;
  - 2. drug name, strength, and quantity;
  - 3. nature of the emergency;
  - 4. time and date of administration;
  - 5. name of prescriber authorizing the medication; and
  - 6. name of person administering the medication.
- G. The correctional center pharmacy shall inspect the EDK periodically, but in no event more than 30 days after the previous inspection. Proper documentation of these inspections, EDK inventory, and all records of use shall be maintained by the correctional center pharmacy and available for review by the board or its agents.

H. The EDK shall be available for inspection by the board or its agents.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1238 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:573 (April 2020).

### §1817. Drug Donations to Correctional Center Pharmacies

- A. A correctional center pharmacy may accept the donation of a prescription drug, except a controlled substance, previously dispensed to another patient provided the following procedures are satisfied:
  - 1. The physical transfer of the donated drug shall be accomplished by an individual authorized to do so by the correctional center pharmacy.
  - 2. An inventory list of the drugs being donated shall accompany the drugs received in the correctional center pharmacy; the list shall contain, at a minimum, the name and strength of the drug, the quantity received, and expiration date. The correctional center pharmacy receiving the donated drugs shall maintain this list as an acquisition record.
  - 3. The correctional center pharmacy shall not knowingly accept the donation of any expired drugs. In the event expired drugs are received by a correctional center pharmacy, the pharmacist-in-charge shall destroy them as required by law.
  - 4. The patient's name, prescription number, and any other identifying marks shall be obliterated from the packaging prior to its receipt in the penal pharmacy.
  - 5. The drug name, strength, and expiration date shall remain on the medication package or label.
- B. The pharmacist-in-charge of the correctional center pharmacy receiving donated drugs shall be responsible for determination of suitability of the drug product for reuse.
  - 1. No product where integrity cannot be assured shall be accepted for re-dispensing by the pharmacist.
  - 2. A re-dispensed prescription medication shall be assigned the expiration date stated on the package.
  - 3. No product shall be re-dispensed more than one time.
- C. Once accepted by the correctional center pharmacy, under no circumstances may the donated drugs be transferred to another location.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1238 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:573 (April 2020).

# §1819. Medication Use Procedures

- A. The pharmacist shall review the practitioner's medical order or prescription prior to dispensing or otherwise provide access to the initial dose of the medication, except in cases of emergency.
- B. All drugs dispensed by the pharmacy or held for administration to offenders at the facility shall be packaged in appropriate containers that comply with the relevant standards of the USP.
- C. The compounding of drug preparations shall comply with the relevant standards of the USP, as well as the provisions of Sections 2531 through 2535 of this Part.
- D. All drugs dispensed by the pharmacy, intended for use within the correctional center, shall be labeled as to identify the offender's name and location as well as the drug name and strength. Further, compounded preparations shall include the expiration date or beyond-use date, initials of the preparer, and initials of the pharmacist performing the final check on the label.
- E. Drugs dispensed by the correctional center pharmacy may be returned to that correctional center pharmacy for re-use, in accordance with good professional practice procedures, subject to the following limitations:
  - 1. Drugs returned to the pharmacy for re-use shall not be further distributed to another entity.
  - 2. Drugs that may be dispensed only to patients registered with the drug manufacturer in accordance with the federal Food and Drug Administration (FDA) requirements shall not be accepted for return or redispensed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1226.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1239 (May 2012), amended by the Department of Health, Board of Pharmacy, LR 46:573 (April 2020).

#### [End of Chapter 18]

#### <u>Note:</u>

<sup>&</sup>lt;sup>1</sup> The statutory list of fees in R.S. 37:1184 is no longer current. The current list of fees is found in Chapter 1 of the administrative code, more specifically in Section 115. The board has not yet revised this chapter to remove the obsolete citations.

# **Chapter 19. Nuclear Pharmacy**

# §1901. Cross References

A. For all regulations that apply to permitted nuclear pharmacies concerning pharmacy practices not specifically stated in this Chapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

# §1903. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section: *Nuclear Pharmacy* – a board-approved facility limited to procuring, possessing, compounding, or dispensing *radiopharmaceuticals* or any interventional drug used in conjunction with nuclear medicine procedures. This definition shall not apply to hospital nuclear medicine departments and nuclear medicine clinics operating under the auspices of a licensed practitioner of medicine.

*Radiation* – any electromagnetic or ionizing *radiation* including gamma rays, X-rays, alpha and beta particles, high-speed electrons, neutrons, protons, and other nuclear particles.

Radioactive Material – any solid, liquid, or gas that emits radiation spontaneously.

*Radiopharmaceutical* – a drug that is a *radioactive material* and includes any drug that is intended to be made radioactive, as defined by the appropriate federal agency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

# §1905. Nuclear Pharmacy Permit Requirements

- A. A nuclear pharmacy permit shall be required to operate a nuclear pharmacy department. The permit shall be applied for, and renewed, in the manner prescribed by the board in Chapter 11 of these regulations.
  - 1. A nuclear pharmacy shall have a Louisiana Radioactive Material License.
  - 2. Nuclear Pharmacist-in-Charge. A pharmacist-in-charge of a nuclear pharmacy operation shall be a qualified nuclear pharmacist, as defined in §1907, and shall be responsible for the entire nuclear pharmacy operation.
  - 3. Structural Requirements. A nuclear pharmacy shall provide adequate space separate and apart from other areas commensurate with the scope of service and with the following space requirements:
    - a. Dispensing Area. The radiopharmaceutical compounding or preparation area shall be separate and apart from other facility areas and shall not be less than 300 square feet, which may include storage and decay areas. The pharmacy area shall be sufficient to provide a work environment for the safe handling, compounding, and dispensing of radiopharmaceuticals. This area shall be separate and inaccessible to non-pharmacy personnel.
    - b. Delivery and Receipt Area. An area designated for the delivery and receipt of materials requiring after-hours handling by non-pharmacy personnel. This area shall be separate from the dispensing area of the pharmacy.
    - c. Storage Area. A storage area sufficient to maintain the scope and content of unused and returned material for decay and disposal commensurate with the compounding and dispensing requirements of the facility.
    - Maintenance. A nuclear pharmacy shall be well maintained, clean, orderly, lighted, and properly ventilated.
    - e. Plumbing. A sink equipped with hot and cold running water shall be located within the nuclear pharmacy. A sink located in a pharmacy lavatory or restroom shall not be sufficient to satisfy this requirement.
  - 4. Equipment. There shall be adequate equipment commensurate with the scope of services required and provided by the facility.
  - 5. Supplies. There shall be adequate supplies commensurate with the compounding and dispensing needs of the facility, as well as any other services provided for by the facility, including appropriate shielding and safety devices and any other supplies necessary for the safe and legal transport of materials compounded or dispensed from the facility. There shall be appropriate supplies for the safe handling and disposal of used and unused material by employees and staff of the facility. The appropriateness of personal protective equipment shall be reviewed on an annual basis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2097 (October 2003), effective January 1, 2004.

## §1907. Qualified Nuclear Pharmacist

- A. A qualified nuclear pharmacist shall be a currently licensed pharmacist in the state of Louisiana who is listed on a Louisiana Radioactive Material License.
- B. Continuing Education. Nuclear pharmacists shall obtain at least five hours of the total required hours of Accreditation Council for Pharmacy Education (ACPE) or board-approved continuing education on those applications and procedures specific to nuclear pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004, LR 33:1133 (June 2007).

## §1909. Labeling

- A. Immediate Container. The immediate container that comes into direct contact with the radiopharmaceutical shall be labeled with:
  - 1. the standard radiation symbol;
  - 2. the words "Caution Radioactive Material";
  - 3. the prescription control number;
  - 4. the name of the radionuclide; and
  - 5. the amount of radioactive material contained, in the appropriate unit of measure.
- B. Outer Container. In addition to any labeling requirements of the board for non-radiopharmaceuticals, the outer container of a radiopharmaceutical to be dispensed shall also be labeled with:
  - 1. the standard radiation symbol;
  - 2. the words "Caution Radioactive Material";
  - 3. the name of the radionuclide;
  - 4. the chemical form:
  - 5. the amount of material contained, in the appropriate unit of measure;
  - 6. the liquid volume expressed in cubic centimeters or milliliters, where applicable; and
  - 7. the calibration time and date for the amount of radioactivity contained.
- C. The labeling requirements in this Section shall not apply to transport containers.
- D. Practitioner Administered Compounds Labeling. All practitioner administered compounds, as defined in Chapter 25 of these regulations, shall be dispensed or delivered in a suitable container with a label containing the following information:
  - 1. pharmacist's name or initials;
  - 2. pharmacy's name, address, and telephone number;
  - 3. preparation name;
  - 4. prescription number or pharmacy-assigned identification number;
  - 5. lot number;
  - 6. beyond use date;
  - 7. strength and concentration;
  - 8. practitioner's name; and
  - 9. special storage requirements, if applicable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

## §1911. Quality Control and Quality Assurance

A. Quality control of radiopharmaceuticals is required on all radiopharmaceuticals compounded in a nuclear pharmacy. Appropriate quality assurance procedures shall be developed and followed for the procurement, compounding, and dispensing of all pharmaceuticals in a nuclear pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

[End of Chapter 19]

# **Chapter 21. Charitable Pharmacy**

# §2101. Cross References

A. For all regulations that apply to permitted charitable pharmacies concerning pharmacy practices not specifically stated in this Chapter, refer to Chapter 11.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

# §2103. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section: *Charitable Pharmacy* – the practice of pharmacy at a site where prescriptions are dispensed by a charitable organization free of charge to appropriately screened and qualified patients. For the purposes of the Louisiana Administrative Code and the <u>Pharmacy Practice Act</u>, a *charitable pharmacy* may at times also be referred to as a *provisional permitted pharmacy*.

Qualified Patients – those patients who are without sufficient funds to obtain medications as determined by strict screening guidelines based on needs assessment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2098 (October 2003), effective January 1, 2004.

## §2105. Charitable Pharmacy Permit Requirements

- A. A charitable pharmacy permit shall be required to operate a pharmacy in the state to dispense free prescription drugs to qualified patients in Louisiana. This permit shall only be granted to an organization qualified as a charitable organization by the U. S. Internal Revenue Code under 26 USC §501(c)(3), or its successor.
- B. Compliance. The charitable pharmacy shall be in compliance with applicable federal, state, and local laws and/or regulations pertaining to the practice of pharmacy.
- C. Guidelines. Strict screening guidelines based on needs assessment shall be developed by the charitable pharmacy to determine who is eligible as a qualified patient.
- D. Review. All screening guidelines, needs assessments, and revisions shall be submitted to the board upon request.
- E. Patient Dispensing. Prescriptions filled in a charitable pharmacy may only be dispensed to qualified patients of that pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2099 (October 2003), effective January 1, 2004.

# §2107. Prescription Drug Samples

- A. A charitable pharmacy shall not sell, purchase, or trade prescription drug samples.
- B. A charitable pharmacy shall only possess and dispense prescription drug samples if the following conditions are satisfied:
  - 1. the prescription drug samples are dispensed at no charge to qualified patients of that charitable pharmacy; and
  - 2. the prescription drug samples are possessed in compliance with the Federal Prescription Drug Marketing Act of 1987, 21 USC §301 et seq., or its successor.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1307 (October 1997), LR 29:2099 (October 2003), effective January 1, 2004.

# §2109. Medication Transfers

A. In facilities licensed by the Department of Health and Hospitals where United States Pharmacopeia (USP) storage requirements can be assured, prescription drugs, except controlled dangerous substances, dispensed in unit dose or in individually sealed doses may be transferred to a permitted charitable pharmacy for relabeling and dispensing to indigent patients, free of charge, pursuant to a valid prescription order.

- 1. The pharmacist-in-charge of the permitted charitable pharmacy shall be responsible for determination of suitability of the product for reuse.
  - a. No product where integrity cannot be assured shall be accepted for re-dispensing by the pharmacist.
  - b. A re-dispensed prescription medication shall be assigned the expiration date stated on the package.
  - c. No product shall be re-dispensed more than one time.
- 2. Pursuant to a voluntary agreement between the facility licensed by the Department of Health and Hospitals and a pharmacy holding a charitable pharmacy permit from the board, prescription drugs, except controlled dangerous substances, may be transferred from the facility to the pharmacy provided the following procedures are satisfied:
  - a. The physical transfer shall be accomplished by an individual authorized to do so by the charitable pharmacy.
  - b. The patient from whom the prescription medication was obtained shall document their consent for the donation; the consent shall be maintained on file at the facility.
  - c. The patient's name, prescription number, and any other identifying marks, shall be obliterated from the packaging prior to removal from the facility.
  - d. The drug name, strength, and expiration date shall remain on the medication package or label.
  - e. An inventory list of the drugs shall accompany the drugs being transferred. The list shall contain, at a minimum, the medication name, strength, quantity, and expiration date.
  - f. Expired drugs shall not be transferred. In the event expired drugs are received by a charitable pharmacy, the pharmacist-in-charge shall destroy them as required by law
- B. Under no circumstances may these transferred medications be re-distributed to another location.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2099 (October 2003), effective January 1, 2004.

#### §2111. Prohibitions

- A charitable pharmacy shall not purchase, possess, trade, distribute, or dispense controlled dangerous substances.
- B. A charitable pharmacy shall not be operated, or in any way associated, with any for-profit pharmacy permitted in this state or any other jurisdiction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2099 (October 2003), effective January 1, 2004.

[End of Chapter 21]

# **Chapter 23. Nonresident Pharmacy**

# §2301. Purpose

- A. Nonresident pharmacies shall comply with the provisions of this Chapter in order to be and remain permitted to operate in Louisiana as a nonresident pharmacy.
- B. This Chapter applies to any place physically located outside the state of Louisiana that provides services in the state of Louisiana where prescription drugs are dispensed and/or pharmacy care is provided to residents of the state of Louisiana. This includes, but is not limited to, pharmacies providing goods and services via U.S. mail carrier, commercial carrier, the Internet, and/or directly to Louisiana residents.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1380 (December 1992) effective January 1, 1993, LR 29:2099 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 49:680 (April 2023).

#### §2303. Nonresident Pharmacy Requirements

- A. The nonresident pharmacy shall hold a current pharmacy permit in good standing in the state in which it is located.
- B. Each pharmacist dispensing drugs into Louisiana shall be licensed as a pharmacist in good standing in the state where he practices.
- C. Every nonresident pharmacy doing business in Louisiana by dispensing and delivering prescription drugs and devices to offenders in the custody of the Louisiana Department of Public Safety and Corrections or local law enforcement agency shall obtain and maintain a nonresident correctional center pharmacy permit, and further, shall comply with the provisions of Chapter 18 of this Part, with the single exception of the necessity for acquiring a separate correctional center pharmacy permit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1380 (December 1992) effective January 1, 1993, LR 29:2100 (October 2003), effective January 1, 2004, LR 39:3074 (November 2013), amended by the Department of Health, Board of Pharmacy, LR 46:574 (April 2020), LR 49:680 (April 2023).

## §2305. Nonresident Pharmacy Permit Requirements

- A. The nonresident pharmacy shall apply for a permit and annual permit renewals on forms provided by the board. The board may require such information as reasonably necessary to carry out the provisions of R.S. 37:1232, including, without limitation, the name, address, and position of each officer and director of a corporation or of the owners, if the pharmacy is not a corporation.
- B. The nonresident pharmacy shall pay an annual permit fee as defined by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1380 (December 1992) effective January 1, 1993, LR 29:2100 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 49:680 (April 2023).

# §2307. Pharmacist-in-Charge

- A. The opportunity to accept an appointment as the pharmacist-in-charge (PIC) of a pharmacy is a professional privilege. The following requirements are attached to a PIC privilege:
  - 1. The acquisition of the PIC privilege shall require:
    - a. possession of an active Louisiana pharmacist license;
    - b. possession of an active license in the state in which the pharmacy is located, and further, said license shall not have any restrictions which prohibit the position of pharmacist-in-charge;
    - c. active practice as a pharmacist for a minimum of two years under the jurisdiction of any board of pharmacy in the United States; and
    - d. the completion of the affidavit of responsibility and duties described in Subsection J of this Section.
  - 2. The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no less than 20 hours per week during the pharmacy's ordinary course of business. In the event the pharmacy's normal hours of business are less than 20 hours per week, the PIC shall be present and practicing at least 50 percent of the normal business hours.

- B. An initial and renewal pharmacy permit application shall designate and identify the licensed pharmacist-incharge.
- C. Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.
- D. Policy and Procedure Manual. The pharmacist-in-charge shall be responsible for the implementation of policies regarding quality pharmacy services including drug control, distribution, patient compliance accountability, inspection, and record keeping.
- E. Circumvention. It is a violation of the pharmacy permit for any person to subvert the authority of the pharmacist-in-charge by impeding the management of the prescription department in the compliance of federal and state pharmacy laws and regulations.
- F. Records. The pharmacist-in-charge is responsible for the proper maintenance of all prescription records. This necessarily includes electronic prescription records and the system's compliance and capacity to produce the required records.
- G. Recall. The pharmacist-in-charge shall be responsible for the implementation of a recall procedure that can be readily activated to assure patient safety.
- H. Discontinued or Outdated Drugs. The pharmacist-in-charge shall be responsible for the implementation of policies and procedures to ensure that discontinued drugs, outdated drugs, or drug containers with worn, illegible, or missing labels are withdrawn from the pharmacy inventory.
- I. Change of Pharmacist-in-Charge. Written notice to the board shall be required when the pharmacist-in-charge designation for a pharmacy has changed.
  - 1. The permit holder shall notify the board within 30 days of the prior pharmacist-in-charge's departure date. The permit holder shall designate a new pharmacist-in-charge within 10 days of the departure of the prior pharmacist-in-charge.
  - 2. The new pharmacist-in-charge shall afford the board written notice of his newly designated pharmacist-in-charge status within 30 days of the departure of the prior pharmacist-in-charge.
  - A pharmacist-in-charge who voluntarily leaves a pharmacy shall give written notice to the board and the
    owner of the permit at least 10 days prior to this voluntary departure, unless replaced in a shorter period
    of time.
- J. Affidavit of Responsibility and Duties. The designated pharmacist-in-charge shall sign an affidavit on a form supplied by the board indicating his understanding and acceptance of the duties and responsibilities of a pharmacist-in-charge. This document shall be submitted to the board for inclusion in the pharmacist's record in the board office.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, LR 29:2100 (October 2003), effective January 1, 2004, LR 33:1133 (June 2007), amended by the Department of Health, Board of Pharmacy, LR 43:50 (January 2017), LR 49:680 (April 2023).

# §2309. Applicable Laws and Regulations

A. Louisiana pharmacy laws and regulations shall be applicable to regulate the practice of pharmacy for that portion of the nonresident pharmacy's Louisiana pharmacy practice or operation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, LR 29:2100 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 49:680 (April 2023).

#### §2311. Inspection

A. The facilities and records of the nonresident pharmacy shall be subject to inspection by the board or its designated agent(s).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, LR 29:2101 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 49:681 (April 2023).

# §2313. Records

- A. Records shall be maintained for not less than two years.
- B. The pharmacy shall maintain records of drugs dispensed to Louisiana residents in such a manner so as to be identifiable, readily retrievable, and available upon request. Said records shall be made available for inspection by the board. The pharmacy permit holder or the pharmacist-in-charge shall produce within 72 hours any information, documentation, and/or records requested by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, LR 29:2101 (October 2003), effective January 1, 2004.

# §2315. Counseling Services

A. The pharmacy shall maintain an incoming toll-free telephone number for use by Louisiana consumers during regular office hours. Readily available telephone counseling services shall be provided that are consistent with the reasonable standard of due care. This telephone number, plus other numbers available for use, shall be printed on each container of drugs dispensed to Louisiana residents. The toll-free telephone number shall have sufficient extensions to provide reasonable access to incoming callers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, LR 29:2101 (October 2003), effective January 1, 2004.

# §2317. Nonresident Pharmacy Closure Procedures

- A. Notice. Notice shall be afforded the board not less than 10 days prior to the anticipated closure date of a nonresident pharmacy. Said notice shall include the location of all transferred prescription files for Louisiana residents.
- B. Permit. The nonresident pharmacy permit holder shall surrender the pharmacy permit to the board upon closure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, LR 29:2101 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 49:681 (April 2023).

# §2319. Jurisdiction

A. Nonresident pharmacies soliciting, receiving, and dispensing and delivering prescription drugs and devices, including controlled dangerous substances as defined in 21 USC §1, et seq. and 21 CFR 1 et seq., or their successors, and delivered to residents in Louisiana constitutes doing business in Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 18:1381 (December 1992) effective January 1, 1993, LR 29:2101 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 49:681 (April 2023).

[End of Chapter 23]

# **Chapter 24. Limited Service Providers**

# Subchapter A. Durable Medical Equipment

# §2401. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section: *Durable Medical Equipment (DME)* – technologically sophisticated medical devices that may be used in a residence, including the following:

- a. oxygen and oxygen delivery system;
- b. ventilators;
- c. respiratory disease management devices;
- d. continuous positive airway pressure (CPAP) devices;
- e. electronic and computerized wheelchairs and seating systems;
- f. apnea monitors;
- g. transcutaneous electrical nerve stimulator (TENS) units;
- h. low air loss cutaneous pressure management devices;
- i. sequential compression devices;
- j. feeding pumps;
- k. home phototherapy devices;
- 1. infusion delivery devices;
- m. distribution of medical gases to end users for human consumption;
- n. hospital beds;
- o. nebulizers; and
- p. other similar equipment as determined by rule.

Legend Device – 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.

Legend Drug -

- 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 diseases in humans or other animals; or
- any substance other than food intended to affect the structure or any function of the body of humans or other animals.

Medical Gas – compressed oxygen and liquid oxygen intended for human consumption.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:502 (March 2013).

## §2403. Durable Medical Equipment (DME) Permit

- A. No person or other entity shall sell, rent or provide, or offer to sell, rent or provide, directly or indirectly, to consumers in this state any durable medical equipment, legend devices, and/or medical gas until such person has obtained a durable medical equipment (DME) permit from the board.
- B. A DME permit shall authorize the permit holder to procure, possess and provide legend devices to the patient or end user; however, the DME permit shall not authorize the permit holder to procure, possess, or provide any prescription or legend drugs.
- C. The board shall not issue a DME permit to any person or other entity that has not registered with the Louisiana Secretary of State to conduct business within the state.
- D. Licensing Procedures
  - 1. A person or other entity desiring to obtain a DME permit shall complete the application form supplied by the board and submit it with any required attachments and the application fee to the board.
  - 2. The applicant shall provide a complete street address reflecting the location where the applicant will hold the equipment and engage in the activity for which the permit is acquired. The board shall not issue more than one permit for the same physical space.
  - 3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.

- 4. A person or other entity who knowingly or intentionally submits a false or fraudulent application shall be deemed to have violated R.S. 37:1241(A)(2).
- 5. Once issued, the DME permit shall expire on August 31 of every year. No person or other entity shall engage in the provision of DME with an expired DME permit.

#### E. Maintenance of Permit

- 1. A DME permit shall be valid only for the person or other entity to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a DME permit be valid for any premises other than the physical location for which it was issued.
- 2. The DME permit holder shall inform the board in writing of any and all changes to its business location within 10 calendar days, with such notice to include both the previous and new addresses.
- 3. A duplicate or replacement permit shall be issued upon the written request of the permit holder and payment of the required fee. A duplicate or replacement permit shall not serve or be used as an additional or second permit.
- 4. A DME provider changing ownership shall notify the board in writing 15 calendar days prior to the transfer of ownership.
  - a. A change of ownership shall be evident under any of the following circumstances:
    - i. sale
    - ii. death of a sole proprietor;
    - iii. the addition or deletion of one or more partners in a partnership;
    - iv. bankruptcy sale; or
    - v. a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original DME permit
  - b. The new owner shall submit a properly completed application form with all required attachments and appropriate fee to the board.
- F. Renewal and Reinstatement of Permit
  - 1. The renewal of an active DME permit shall require the submission of a completed application form supplied by the board supplemented with any required attachments and appropriate fee, prior to the expiration date of the permit.
  - 2. The reinstatement of an expired DME permit shall require the submission of a completed application form supplied by the board supplemented with any required attachments as well as the renewal and reinstatement fee.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:502 (March 2013).

## §2405. Standards of Practice

- A. The DME provider shall not furnish any legend device or medical gas to a patient without a prescription or medical order from a licensed practitioner with prescriptive authority.
- B. General Requirements
  - 1. The provider shall establish a suitable facility to house the equipment, allow for equipment maintenance work space, and contain sufficient space for the storage and retrieval of all required records.
  - 2. The provider shall maintain the facility in a clean, orderly and sanitary condition at all times.
  - 3. The facility shall be equipped with a functioning lavatory with hot and cold running water, or in the alternative, hand washing appliances or waterless hand cleaner are available.
  - 4. The facility shall comply with all local and state building laws and fire codes.
  - 5. The provider shall comply with all requirements from the United States Pharmacopeia (USP), the federal Food and Drug Administration (FDA), federal Department of Transportation (DOT) and Occupational Safety and Health Administration (OSHA) relative to the storage, packaging, labeling and shipping of DME including medical gases.
  - 6. The provider shall staff the facility with an adequate number of qualified personnel to properly render DME services in the manner prescribed by law.
  - 7. The provider shall make services continuously available without interruption when such services are essential to the maintenance of life or when the lack of services might reasonably cause harm.
  - 8. The provider shall implement and maintain written procedures for handling complaints, and further, shall maintain a complaint file documenting all complaints and their resolution.
- C. Requirements for Providers of Medical Gas, Oxygen and Respiratory Equipment
  - 1. The provider shall comply with the following:
    - a. when transporting medical gas or oxygen in cylinder or liquid form, comply with all current DOT rules;

- b. when trans-filling medical oxygen systems, comply with FDA and all state agency requirements regarding trans-filling and repackaging;
- c. demonstrate that medical gas and oxygen provided in cylinder or liquid form meet minimum purity standards for medical grade gas or medical grade oxygen; and
- d. adhere to the following safety inspection requirements:
  - i. demonstrate that each piece of oxygen or respiratory equipment has been checked, is free of defects, and operates within the manufacturer's specifications;
  - ii. refrain from modifying equipment to the extent that the modification might reasonably cause harm:
  - iii. maintain all electrical components so they do not present fire or shock hazard; and
  - v. ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.
- 2. The provider shall comply with the following recall procedures:
  - a. ensure that lot numbers and expiration dates are affixed to each cylinder delivered;
  - b. maintain a tracking system for all medical gas and oxygen delivered;
  - c. document all equipment serial numbers and model numbers to ensure that equipment can be retrieved in the event a recall is initiated; and
  - d. maintain records for equipment that requires FDA tracking.
- 3. The provider shall comply with the following maintenance and cleaning requirements:
  - a. maintain documentation demonstrating that a function and safety check of equipment was performed prior to set-up;
  - b. maintain and established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;
  - c. maintain a material safety data sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures;
  - d. maintain segregated areas on the premises and in delivery vehicles for clean, dirty and contaminated equipment;
  - e. clean and disinfect equipment according to manufacturers' specifications;
  - f. instruct the patient or caregiver on proper cleaning techniques as specified by the manufacturer; and
  - g. ensure that all medical gas, oxygen and respiratory equipment are properly identified by a tag or label as to its current status of use, i.e., out-of-order or ready for use.
- 4. The provider shall implement a comprehensive preventive maintenance program which shall include the following:
  - a. procedures for problem reporting, tracking, recall, and resolution;
  - b. performance of service as specified by the manufacturer and the documentation of such performance in the service records; and
  - c. routine inspection, service, and maintenance of equipment located in the patient's home according to the manufacturer's specifications.
- 5. The provider shall maintain repair logs to document repair and maintenance of equipment, and such logs shall contain the following information:
  - a. type of equipment;
  - b. manufacturer;
  - c. model;
  - d. serial number;
  - e. date of repair;
  - f. specific repair made; and
  - g. name of person or company performing the repair.
- 6. The provider shall maintain testing equipment to ensure accurate calibration. Testing equipment shall be appropriate for the level of service offered. Scales used to weigh liquid oxygen reservoirs shall be properly maintained to ensure accuracy.
- 7. The provider shall utilize client orientation checklists to review the following information with the patient or caregiver:
  - a. instructions for use of the equipment;
  - b. safety precautions;
  - c. cleaning procedures;
  - d. maintenance procedures;
  - e. return demonstration on back-up oxygen systems delivered;
  - f. instruction for emergency and routine contact procedures; and

- g. delivery and review of written instruction materials to ensure the patient receives adequate information to properly operate the equipment.
- 8. A written plan of service shall be developed, implemented, and documented in the patient record. The plan of service shall include, but is not limited to, an assessment of the safety of the home environment, the ability of the patient or caregiver to comply with the prescription or medical order, and the ability of the patient or caregiver to operate and clean the equipment as instructed.
- D. Requirements for Providers of Other Durable Medical Equipment
  - 1. Providers who sell, rent or furnish DME or legend devices shall comply with the following:
    - a. provide proper training to personnel for the safe delivery and use of any DME or legend device; and
    - b. ensure that all manufacturer's recommended assembly and maintenance procedures are followed; and
    - c. adhere to the following safety inspection measures:
      - demonstrate that each piece of DME or legend device has been checked, is free of defect and operates within the manufacturer's specifications;
      - ii. refrain from modifying equipment to the extent that the modification might reasonably cause harm;
      - iii. maintain all electrical components so they do not present fire or shock hazard; and
      - iv. ensure that all appropriate warning labels or labeling, including tags, are present on the equipment provided.
  - 2. The provider shall comply with the following maintenance and cleaning requirements:
    - n. maintain documentation demonstrating that a function and safety check of equipment was performed prior to set-up;
    - b. maintain an established protocol for cleaning and disinfecting equipment which addresses both aerobic and anaerobic pathogens;
    - c. maintain a material safety data sheet (MSDS) on file for solutions and products used in cleaning and disinfecting procedures;
    - d. maintain segregated areas on the premises and in delivery vehicles for clean, dirty and contaminated equipment;
    - e. clean and disinfect equipment according to manufacturers' specifications; and
    - f. instruct the patient or caregiver on proper cleaning techniques as specified by the manufacturer.
- E. Records Management for All DME Providers
  - 1. An electronic record keeping system shall be implemented and maintained by the provider. The system shall provide adequate safeguards against unauthorized access, manipulation or alteration, and further, shall be susceptible to reconstruction in the event of electronic or computer malfunction or an unforeseen accident resulting in the destruction of the system or the information contained therein.
  - 2. All records required in this Chapter shall be retained for a minimum of two years from the last transaction.
  - 3. All records required in this Chapter shall be available and readily retrievable upon request for board inspection and review. In particular, such records shall be produced within 72 hours of the request.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:503 (March 2013).

# §2407. Exemptions

- A. The credentialing requirements of this Subchapter shall not apply to the following persons or entities unless such persons or entities have separate business entities engaged in the business of providing DME to patients at their home:
  - 1. chiropractors;
  - 2. dentists;
  - 3. occupational therapists;
  - 4. optometrists;
  - 5. physical therapists;
  - 6. physicians;
  - 7. podiatrists;
  - 8. respiratory therapists;
  - 9. speech pathologists;
  - 10. veterinarians;
  - 11. distributors;
  - 12. home health agencies;
  - 13. hospice programs;

- 14. hospitals;
- 15. long term care facilities;
- 16. manufacturers; and
- 17. pharmacies.
- B. Pharmacies, although excluded from the credentialing requirements of this Subchapter, shall be subject to and comply with the standards of practice identified herein.
- C. Nothing in this Subchapter shall be construed to prohibit the pre-hospital emergency administration of oxygen by licensed health care providers, emergency medical technicians, first responders, fire fighters, law enforcement officers and other emergency personnel trained in the proper use of emergency oxygen.

AUTHORITY NOE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 39:504 (March 2013).

# **§2409.** (Reserved)

# **Subchapter B. Special Event Pharmacy Permit**

# §2411. Special Event Pharmacy Permit

A. For good cause shown, the board may issue a special event pharmacy permit when the scope, degree, or type of pharmacy practice or service to be provided is of a special, limited, or unusual nature as compared to a regular pharmacy service. The permit to be issued shall be based on special conditions as requested by the applicant and imposed by the board in cases where certain requirements or standards of practice may be waived.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1223.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:100 (January 2015).

# §2413. General Requirements

- A. Authority and Limitation
  - 1. A special event pharmacy permit shall authorize the permit holder to procure and possess prescription and non-prescription drugs and devices, and hold such items for immediate administration directly to a patient and/or dispense such items to a patient for later use upon the order of a practitioner with prescriptive authority.
  - 2. In the absence of a Louisiana controlled dangerous substance (CDS) license, the holder of a special event pharmacy permit shall not procure or possess any controlled dangerous substances.
- B. Licensing Procedure
  - 1. A person or other entity desiring to obtain a special event pharmacy permit shall complete the application form supplied by the board and submit it with any required attachments and the application fee to the board
  - 2. The applicant shall provide a complete physical address reflecting the location where the applicant will hold the drugs and devices and engage in the activity for which the permit is acquired. The board shall not issue more than one permit for the same physical space.
  - 3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
  - 4. A person or other entity who knowingly or intentionally submits a false or fraudulent application shall be deemed to have violated R.S. 37:1241(A)(2).
  - 5. Once issued, the special event pharmacy permit shall expire 30 days thereafter. No person or other entity shall operate s special event pharmacy with an expired permit; the continued operation of a special event pharmacy with an expired permit shall constitute a violation of R.S. 37:1241(A)(12). Upon written request to the board, and with the concurrence of the board's president and executive director, the expiration date of the special event pharmacy permit may be extended up to an additional 30 days. No special event pharmacy permit shall be valid for more than 60 days.

#### C. Maintenance of Permit

- 1. A special event pharmacy permit shall be valid only for the person or other entity to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a special event pharmacy permit be valid for any premises other than the physical location for which it is issued.
- 2. A duplicate or replacement permit shall be issued upon the written request of the permit holder and payment of the required fee. A duplicate or replacement permit shall not serve or be used as an additional or second permit.

#### D. Closure of Permit

- 1. At the conclusion of the special event, the permit holder shall terminate the dispensing and/or distribution of drugs and/or devices from the pharmacy.
- 2. Disposition of Inventory
  - a. Controlled Dangerous Substances Listed in Schedule II. These drugs shall be either returned to the supplier or transferred to an authorized registrant, accompanied by an executed <u>DEA Form 222</u>, or its successor. Alternatively, these drugs shall be inventoried on the <u>DEA Form 41</u> (registrant's inventory of drugs surrendered), or its successor, and then either returned to the regional DEA office or destroyed, but only pursuant to permission from the DEA or agent of the board. The permit holder shall retain triplicate copies of returns, transfers, and/or destructions.
  - b. Controlled Dangerous Substances Listed in Schedules III, IV, or V. These drugs shall be either returned to the supplier or transferred to an authorized registrant, accompanied by appropriate inventory records. Alternatively, these drugs shall be inventoried on the <u>DEA Form 41</u>, or its successor, and then either returned to the regional DEA office, or destroyed pursuant to permission from the DEA or agent of the board.
  - c. All Other Prescription and Non-prescription Drugs and/or Devices. These items shall be returned to the supplier, transferred to another registrant, or destroyed.
- 3. Surrender of Credentials and Board Notice
  - a. When all drugs, devices, prescription records and other pharmacy records have been removed from the premises, the permit holder shall prepare and render a final closure notice to the board. The notice shall contain the following:
    - i. disposition and destination of all drugs and/or devices held by the pharmacy;
    - ii. disposition and destination of all prescriptions and medical orders dispensed or administered to patients;
    - iii. disposition and destination of all other pharmacy records, including acquisition, inventory, and disposition records for all drugs and/or devices;
    - iv. the commitment to store such records for no less than two years following the closure of the pharmacy, and further, to make such records available for inspection by the board no later than 72 hours following a request from the board.
    - v. the certification that all signage indicating the presence of a pharmacy has been removed from the premises;
    - vi. the confirmation of the surrender of any federal DEA registration held by the pharmacy to the regional DEA office; and
    - vii. the original and all duplicate copies of the special event pharmacy permit, and if applicable, Louisiana CDS license.
  - b. The pharmacist-in-charge of the special event pharmacy permit has the primary responsibility for the proper closure of the pharmacy permit. However, in the event the pharmacist-in-charge fails to complete the task, then the permit holder shall be responsible for the proper closure of the pharmacy permit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:100 (January 2015).

#### §2415. Standards of Practice

- A. General Requirements
  - 1. The special event pharmacy shall be of sufficient size and shall contain sufficient fixtures, equipment, and supplies commensurate with the scope of practice for that pharmacy, provided:
    - a. the pharmacy shall be of sufficient size to allow for the safe and proper storage of prescription drugs and, if applicable, controlled dangerous substances;
    - b. all areas where drugs and devices are stored shall be dry, well-lighted, well ventilated, and maintained at temperatures which will ensure the integrity of drugs prior to their dispensing as stipulated by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product labeling unless otherwise indicated by the board;
    - c. the pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry at a time when the pharmacist is not present; and
    - d. prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information.
  - 2. The pharmacist-in-charge of the special event pharmacy shall be responsible for all pharmacy operations including supervision of all pharmacy personnel.

- 3. The pharmacy shall have at least one licensed pharmacist on duty and physically present in the pharmacy at all times the pharmacy is open for the transaction of business.
- 4. The pharmacy shall have a sufficient number of pharmacists and/or other pharmacy personnel on duty to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the pharmacy.
- 5. When the pharmacy is closed or there is no pharmacist on duty, other individuals shall not have access to the pharmacy except for temporary absences as provided for in Chapter 11 of these rules.
- 6. The special event pharmacy shall comply with the recordkeeping requirements identified in Chapter 11 of these rules.
- 7. The compounding of preparations in a special event pharmacy shall be accomplished in compliance with the current federal standards applicable to such practices: USP Chapter 795, or its successor, for the compounding of non-sterile preparations and USP Chapter 797, or its successor, for the compounding of sterile preparations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:101 (January 2015).

## Subchapter C. Telepharmacy Services

## §2421. Purpose

- A. As market forces continue to adversely impact community pharmacies, some pharmacies have or will close permanently. In certain parts of the state, such closures create critical access issues for citizens in need of pharmacy services.
- B. As the pharmacy workforce continues to evolve, with changing patterns of distribution of the workforce, certain parts of the state have experienced a shortage of pharmacists, which can adversely impact access to pharmacist care.
- C. In an effort to improve access to pharmacist care and pharmacy services, the board has determined it appropriate to establish standards for the operation and regulation of telepharmacy services

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2149 (October 2015).

## §2423. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section: Central Pharmacy – a permitted pharmacy in Louisiana that supervises a telepharmacy dispensing site.

Still Image Capture – a specific image captured electronically from a video or other image capture device.

Store and Forward – a video or still image record which is saved electronically for future review.

Telepharmacy Dispensing Site – a permitted pharmacy supervised by a central pharmacy that offers pharmacy services using a telepharmacy system.

*Telepharmacy System* – a system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method which shall include the use of the following types of technology:

- a. audio and video;
- b. still image capture; and
- c. store and forward.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2149 (October 2015).

# §2425. Telepharmacy Dispensing Site

- A. General Requirements
  - 1. At the time of its opening, there shall be no other pharmacies licensed by the board within 15 miles (driving distance) of the location of the telepharmacy dispensing site. This mileage restriction shall not apply if a demonstration of need is presented to the board and a waiver to the mileage restriction is deemed appropriate.
  - 2. A telepharmacy dispensing site permit shall authorize the permit holder to procure and possess prescription and non-prescription drugs and devices, and:

- a. hold such items for immediate administration directly to a patient pursuant to an order from a lawful prescriber:
- b. dispense such items to a patient for later use upon the order of a practitioner with prescriptive authority; or
- c. distribute such items to another entity with lawful authority to procure and possess such items.
- 3. In the event the telepharmacy dispensing site intends to procure and possess any controlled substances, that pharmacy shall first obtain a Louisiana controlled dangerous substance license as well as the federal registration from the U.S. Drug Enforcement Administration.
- 4. The telepharmacy dispensing site shall operate using a telepharmacy system under the control of its supervising central pharmacy.
- 5. A central pharmacy may supervise no more than two telepharmacy dispensing sites, and all such sites must be located within the state of Louisiana.
- 6. The minimum staffing requirement for a telepharmacy dispensing site shall be a Louisiana-licensed certified pharmacy technician with at least two years of experience as a Louisiana-licensed certified pharmacy technician and with demonstrated proficiency in operating the telepharmacy system used in the telepharmacy dispensing site.
- 7. A pharmacist shall approve each prescription before it is taken away from the telepharmacy dispensing site.

#### B. Licensing Procedure

- 1. A person or other entity intending to operate a telepharmacy dispensing site shall complete the application form supplied by the board, and then submit it with any required attachments and the application fee to the board.
- 2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
- 3. A person or other entity who submits a false or fraudulent application shall be deemed to have violated R.S. 37:1241(A)(2) and shall be subject to disciplinary action by the board.
- 4. If determined appropriate by the board, the applicant may be required to meet with a committee of the board or an agent of the board prior to the issuance of the permit.
- 5. Regardless of the date issued, the pharmacy permit shall expire on December 31 of every year. No person or other entity may operate a telepharmacy dispensing site with an expired permit; the continued operation of a telepharmacy dispensing site with an expired permit shall substantiate a violation of R.S. 37:1241(A)(12).
- 6. In the event a telepharmacy dispensing site is dispensing more than 100 prescriptions per day based on a six-month average, the telepharmacy dispensing site shall convert its permit to a community pharmacy permit prior to the expiration date of the telepharmacy dispensing site permit.

### C. Maintenance of Permit

- 1. A telepharmacy dispensing site permit shall be valid only for the person or other entity to whom it is issued, and it shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit be valid for any premises other than the physical location for which it was issued.
- 2. A duplicate or replacement permit shall be issued upon the written request of the permit holder and payment of the required fee. A duplicate or replacement permit shall be marked as such, and it shall not serve or be used as an additional or second permit.

## D. Closure of Permit

- 1. When the owner of the permit intends to close the telepharmacy dispensing site permanently, the owner's managing officer and the pharmacist-in-charge shall be accountable to the board for the proper closure of the pharmacy in compliance with §1133 of this Part.
- 2. Unless approved by the board in advance, all remaining inventory and records shall be transferred to the central pharmacy supervising that telepharmacy dispensing site.

#### E. Standards of Practice

## 1. Environmental Standards

- a. The prescription department shall consist of sufficient space commensurate with the nature and scope of the pharmacy's practice; this space shall be restricted to authorized personnel only and not accessible to the general public.
- b. The prescription department shall contain sufficient fixtures, equipment, and supplies commensurate with the nature and scope of practice for that pharmacy.
- c. The prescription department shall include a sink with a hot and cold water supply, exclusive of restroom facilities, with approved sewage disposal.
- d. All areas where drugs and devices are stored shall be dry, well-lighted, well ventilated, and maintained at temperatures which will ensure the integrity of drugs prior to their dispensing as

- stipulated by the United States Pharmacopeia and/or manufacturer's or distributor's product labeling unless otherwise indicated by the board.
- e. The prescription department shall be secured by a physical barrier with suitable locks and a monitored alarm system capable of detecting unauthorized entry.
- f. Prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information; and
- g. The dispensing site shall be configured and equipped to sustain optimal operation of all the technological components of the telepharmacy system.

#### 2. Minimum Staffing Requirements

- a. The pharmacist-in-charge of the supervising central pharmacy shall be the pharmacist-in-charge of the telepharmacy dispensing site, and this requirement shall operate as an exception to the contrary provisions of §1105 of this Part. However, the pharmacist-in-charge shall comply with the remaining provisions of §1105 of this Part.
- b. The telepharmacy dispensing site does not require the personal presence of a pharmacist, but it is permissible for a pharmacist to practice in that site.
- c. In the absence of a pharmacist, the site shall be staffed by one, and only one, Louisiana-licensed certified pharmacy technician. The technician present at the telepharmacy dispensing site shall be included with the other personnel at the supervising central pharmacy when calculating the ratio of pharmacists to technicians.
- d. A pharmacy intern or pharmacy technician candidate may not practice at a telepharmacy dispensing site.
- e. Additional clerical personnel may also be present at the site.

#### 3. Operational Standards

- a. The telepharmacy dispensing site shall comply with the provisions of Chapters 11, 25, 27, and 29 of this Part except when this Subchapter grants exceptions or imposes more stringent requirements.
- b. The telepharmacy dispensing site shall be connected to its supervising central pharmacy using the telepharmacy system.
- c. In the event of an interruption in the proper operation of the telepharmacy system, the telepharmacy dispensing site must immediately cease operations. No prescription shall be dispensed during the interruption, and further, the staff shall post a sign at the entrance advising the public of an estimated date or time of resumption of services.
- d. The dispensing of prescriptions shall be construed as completed at the central pharmacy; therefore, the telepharmacy dispensing site shall use the central pharmacy's dispensing information system.
- e. The telepharmacy system shall permit prescription labels to be generated from the central pharmacy or the telepharmacy dispensing site.
  - i. new prescriptions may be received and entered at the central pharmacy with a label printed at the telepharmacy dispensing site; or
  - ii. new prescriptions received at the telepharmacy dispensing site may be entered by the technician with all verification, utilization review, and final check the responsibility of the pharmacist at the central pharmacy.
- f. As part of the final check, the pharmacist shall verify the source container, prescription medication, and prescription label against the prescription form, using the technology in the telepharmacy system.
- g. A pharmacist shall comply with the rules for drug utilization review and patient counseling in Chapter 5 of this Part, using HIPAA compliant technology in the telepharmacy system.
- h. The pharmacist-in-charge shall be responsible for routine inspections of the telepharmacy dispensing site. The policies and procedure shall identify the inspection criteria to be monitored. Each inspection shall be conducted no later than 30 days after the previous inspection. The inspection reports detailing the findings of each inspection shall be retained for at least two years, and further, shall be readily retrievable upon request by the board or its agent.

## 4. Recordkeeping Requirements

- a. The dispensing information system shall be capable of recording the names or initials of the pharmacist responsible for final verification of the prescription as well as the technician assisting in the dispensing process, and to print those identities on the prescription label.
- b. Prescriptions filled at the telepharmacy dispensing site shall be distinguishable on records from those filled at the central pharmacy.
- c. Records of activities at the telepharmacy dispensing site shall be distinguishable from the records of activities at the central pharmacy.
- d. Telepharmacy dispensing sites holding controlled substances shall maintain a perpetual inventory of controlled dangerous substances and drugs of concern.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 21:2149 (October 2015), amended by the Department of Health, Board of Pharmacy, LR 46:586 (April 2020), LR 47:1643 (November 2021).

# Subchapter D. Remote Processor Pharmacy

## §2431. Purpose

A. The purpose of this Subchapter is to establish standards for the operation and regulation of remote processor pharmacies to be located within the state of Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2148 (October 2015).

## §2433. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section: *On-Site Pharmacy* – a permitted pharmacy which utilizes remote processing services from a remote processor pharmacy.

Remote Processing Services – the processing of a medical order or prescription drug order by one permitted pharmacy on behalf of another permitted pharmacy, including:

- a. receipt, interpretation, or clarification of an order;
- b. data entry and information transfer;
- c. interpretation of clinical data;
- d. performance of drug utilization review; and
- e. provision of drug information concerning a patient's drug therapy; provided, however, that remote processing does not include the physical preparation or physical transfer of drugs.

*Remote Processor* – a pharmacy holding a remote processor pharmacy permit and provides remote processing services for another permitted pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2148 (October 2015).

## §2435. General Requirements

- A. Authority and Limitations
  - A remote processor pharmacy permit shall authorize the permit holder to engage in remote processing services.
  - 2. A remote processor pharmacy permit shall not authorize the procurement or possession of any prescription medications or any controlled substances.
  - 3. The holder of a remote processor pharmacy permit shall not be eligible to acquire a Louisiana controlled dangerous substances license or a federal registration from the U.S. Drug Enforcement Administration.
- B. Licensing Procedure
  - 1. A person or other entity intending to operate a remote processor pharmacy shall complete the application form supplied by the board, and then submit it with any required attachments and the application fee to the board.
  - 2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
  - 3. A person or other entity who submits a false or fraudulent application shall be deemed to have violated R.S. 37:1241(A)(2) and shall be subject to disciplinary action by the board.
  - 4. If determined appropriate by the board, the applicant may be required to meet with a committee of the board or an agent of the board prior to the issuance of the permit.
  - 5. Regardless of the date issued, the pharmacy permit shall expire on December 31 of every year. No person or other entity may operate a remote processor pharmacy with an expired permit; the continued operation of a remote processor pharmacy with an expired permit shall substantiate a violation of R.S. 37:1241(A)(12).
- C. Maintenance of Permit
  - 1. A remote processor pharmacy permit shall be valid only for the person or other entity to whom it is issued, and it shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall

- the permit be valid for any premises other than the physical location for which it was issued.
- 2. A duplicate or replacement permit shall be issued upon the written request of the permit holder and payment of the required fee. A duplicate or replacement permit shall be marked as such, and it shall not serve or be used as an additional or second permit.

#### D. Closure of Permit

1. When the owner of the permit intends to close the remote processor pharmacy permanently, the owner's managing officer and the pharmacist-in-charge shall be accountable to the board for the proper closure of the pharmacy in compliance with Section 1133 of the board's rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2148 (October 2015).

# §2437. Standards of Practice

#### A. Environmental Standards

- 1. The remote processor pharmacy shall be of sufficient size and shall contain sufficient fixtures, equipment, and supplies commensurate with the nature and scope of practice for that pharmacy.
- 2. The pharmacy shall be well-lighted, well ventilated and in compliance with the Louisiana Sanitary Code.
- 3. The pharmacy shall be secured by either a physical barrier with suitable locks and/or an electronic barrier to detect entry by any unauthorized personnel.
- 4. Prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information.

#### B. Staffing Requirements

- 1. The pharmacist-in-charge shall be a Louisiana-licensed pharmacist who is accountable to the board for compliance with the provisions of Section 1105 of the board's rules.
- 2. The pharmacist-in-charge shall assemble and manage a staff of appropriately-credentialed people as necessary to perform its work in a safe manner.
- 3. For those pharmacies using pharmacy interns, pharmacy technicians, and pharmacy technician candidates, the staffing ratios cited in the board's rules are applicable to those types of personnel.

#### C. Operations

- 1. The remote processor pharmacy shall comply with the provisions of Section 1143 of the board's rules.
- 2. The remote processor shall comply with the recordkeeping provisions of Section 1123 of the board's rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 41:2149 (October 2015).

# Subchapter E. Marijuana Pharmacy

## §2440. Preamble; Warning; Consultation Suggested

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1538 (August 2017), amended LR 48:1902 (July 2022), repealed LR 49:1719 (October 2023).

# §2441. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section: *Administer* – the direct application of marijuana to the body of a qualifying patient by ingestion or any other means. *Advertisement* – *repealed*.

Agent – an authorized person who acts on behalf of or at the direction of another person. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

Approved Safe – repealed.

*Approved Vault – repealed.* 

Authorized Clinician – licensed health professionals authorized pursuant to R.S. 40:1046.

Board – the Louisiana Board of Pharmacy.

*CFR* – the Code of Federal Regulations.

*Delivery* or *Delivery* – the actual, constructive or attempted transfer from one person to another of marijuana, whether or not there is an agency relationship.

Financial Interest – any actual, or a future right to, ownership or investment, either directly or indirectly, through business, investment or immediate family. Financial interest does not include ownership of investment securities in a publicly-held corporation that is traded on a national exchange or over-the-counter market, provided the investment securities held by such person do not exceed 5 per cent of the total number of shares issued by the corporation.

Immediate Family – R.S. 42:1102, i.e., his children and the spouses of his children, his brothers and their spouses, his sisters and their spouses, his parents, his spouse, and the parents of his spouse.

*LDAF – repealed. LDH –* the Louisiana Department of Health.

Louisiana Medical Marijuana Tracking System (LMMTS) – the required seed-to-sale tracking system that tracks medical marijuana from either the seed or immature plant stage until the product is sold to a pharmacy or is destroyed.

*Marijuana Pharmacy* – that area within a facility where marijuana is stored, dispensed, and sold. If a facility does not offer any products or services other than marijuana and/or related supplies, the entire facility is a marijuana pharmacy for the purposes of this Subchapter.

Marijuana Pharmacy Owner – any person with an ownership interest in a marijuana pharmacy, except the term does not include a person with an investment interest through a publicly-held company provided the interest held by such person does not exceed five percent of the total ownership or interest rights in such pharmacy and such person does not participate directly or indirectly in the control, management, or operation of the pharmacy.

*Marijuana Product* – any product containing marijuana, including raw materials, that requires no further processing and that is packaged for sale to pharmacies, qualifying patients and primary caregivers.

Owner's Managing Officer – the person designated by the organization owning the pharmacy to be responsible to the board for the proper operation of the pharmacy in compliance with all applicable laws and regulations.

Pharmaceutical Grade Marijuana - marijuana or marijuana products that are not adulterated and are:

- a. processed, packaged and labeled according to the United States Food and Drug Administration's "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements" as found in <u>21 CFR 111</u> or its successor;
- b. labeled with the results of an active ingredient analysis, a microbiological contaminants analysis, a mycotoxin analysis, a heavy metal analysis, and a pesticide chemical residue analysis which have been completed on a batch basis by a laboratory; and
- c. where each step of the production, cultivating, trimming, curing, manufacturing, processing, and packaging method has been documented by using standard operation procedures verified by the Louisiana Department of Health.

*Pharmacist* – an individual currently licensed by the board to engage in the practice of pharmacy.

*Pharmacy Technician* – an individual who assists in the practice of pharmacy under the direct and immediate supervision of a licensed pharmacist and is currently certified to do so by the board.

Physician – repealed.

Prescription Monitoring Program (PMP) – the electronic prescription drug monitoring program established by R.S. 40:1001 et sea.

*Producer* – a person licensed by the Department of Health to cultivate marijuana for therapeutic use.

*Production* or *Produce* – the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, compounding, conversion or processing of marijuana, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of marijuana by a patient or caregiver for the patient's use.

*Production Facility* – a secure facility where the production of marijuana occurs and that is operated by a person to whom the Department of Health has issued a producer license.

Sale – any form of delivery, which includes barter, exchange or gift, or offer therefor, and each such transaction made by any person whether as principal, proprietor, agent, servant, or employee.

*Usable Marijuana* – the dried leaves and flowers of the marijuana plant, and any mixtures or preparations of such leaves and flowers, that are appropriate for the therapeutic use of marijuana, but does not include the seeds, stalks, and roots of the marijuana plant.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1538 (August 2017), amended LR 45:1473 (October 2019), LR 46:1227 (September 2020), LR 49:1719 (October 2023).

# §2443. Marijuana Products

- A. Exclusive Source
  - 1. The exclusive source of marijuana products shall be the producers licensed for that activity by LDH.
  - Repealed.
  - 3. Marijuana products from any other source shall be deemed misbranded and/or adulterated and shall not be received by any marijuana pharmacy, nor may such misbranded and/or adulterated products be dispensed by any marijuana pharmacy.
- B. Laboratory Testing
  - 1. Repealed.
  - 2. Repealed.
  - 3. Repealed.
  - 4. Repealed.
  - 5. Repealed.
  - 6. Repealed.
  - 7. Repealed.
  - 8. The marijuana pharmacy shall have access to the laboratory test results from the producer for each final product acquired by the marijuana pharmacy. The pharmacy shall make such testing results available upon request to their patients, caregivers, and authorized clinicians who recommended such marijuana products dispensed to their patients.

#### C. Product Dosage Forms

- 1. The marijuana pharmacy shall limit their dispensing of pharmaceutical grade products to the following dosage forms:
  - a. oils, extracts, tinctures, or sprays;
  - b. solid oral dosage forms, e.g., capsules or pills;
  - c. liquid oral dosage forms, e.g., solutions or suspensions;
  - d. gelatin-based or pectin-based chewables;
  - e. topical applications, oils or lotions;
  - f. transdermal patches;
  - g. suppositories; or
  - h. metered-dose inhalers.
  - i. repealed.
- 2. The marijuana pharmacy may dispense other products from raw or crude marijuana, including dried flower, buds, and other plant material, intended for the following methods of administration:
  - a. combustible forms for inhalation, including but not limited to pre-rolls; and
  - b. edible forms for ingestion.
- 3. No marijuana product shall:
  - a. include alcoholic liquor, dietary supplements, or any drug, except for marijuana. For purposes of this provision, alcoholic liquor does not include any liquid or solid containing less than 0.5 percent of alcohol by volume, or ethanol-based tinctures;
  - b. be manufactured or sold in a form or with a design that:
    - i. is obscene or indecent;
    - ii. may encourage the use of marijuana for recreational purposes;
    - iii. may encourage the use of marijuana for a condition other than a debilitating medical condition; or
    - iv. is customarily associated with persons under the age of 18 years; or
  - c. have had pesticide chemicals or organic solvents used during the production or manufacturing process other than those which may be approved for use by LDH.
- 4. Any marijuana product not in compliance with the provisions of this Section shall be deemed adulterated.
- D. Repealed.
- E. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1540 (August 2017), amended LR 45:1473 (October 2019), LR 46:568 (April 2020), LR 46:1227 (September 2020), LR 47:590 (May 2021), LR 48:1902 (July 2022), LR 49:1719 (October 2023).

# §2445. Marijuana Pharmacy Permit

- A. The board shall develop and configure a pharmacy permit designated as a marijuana pharmacy permit.
- B. The dispensing of marijuana for therapeutic purposes shall be limited to those pharmacies holding a marijuana

- pharmacy permit issued by the board, and only when that permit is in active or restricted status.
- C. When issued to a successful applicant, the permit will authorize the operation of a marijuana pharmacy in compliance with the provisions of this Subchapter.
- D. When the permit is issued, it shall be valid only for the owner and the specific location noted on the application and recorded on the permit.
- E. A marijuana pharmacy permit is non-transferable from one owner to another owner, and moreover, in the event the ownership of the organization that acquired the permit changes by 50 percent or more, then the ownership will be deemed sufficiently different as to require a new marijuana pharmacy permit. A marijuana pharmacy permit owner continuing to operate a marijuana pharmacy after its ownership has changed by 50 percent or more without obtaining a new marijuana pharmacy permit shall be subject to disciplinary review by the board.
- F. Although a change of ownership of less than 50 percent shall not require a new pharmacy permit, any proposed change of ownership shall require prior notice to the board, and further, approval by the board.
- G. Repealed.
- H. Repealed.
- I. When the board is prepared to receive and process applications for and issue marijuana pharmacy permits, it shall publish on its internet web site, and in such other places as the board deems appropriate, a notice to that effect. Such notice shall include, but not be limited to:
  - 1. the maximum number of permits to be awarded;
  - 2. information on how to obtain an application;
  - 3. the deadline for receipt of applications;
  - 4. acceptable methods for submitting an application;
  - 5. the preferred locations, if any, for the marijuana pharmacy permits; and
  - 6. the criteria that shall be considered in awarding the marijuana pharmacy permits.
- J. Following the deadline for receipt of applications, the board shall evaluate each complete and timely submitted application and award marijuana pharmacy permits on a competitive basis based on the criteria set out in the notice for applications. In the event the board determines there are an insufficient number of qualified applicants to award all of the marijuana pharmacy permits the board has determined are desirable, the board may republish, in accordance with this Section, a notice of open applications for marijuana pharmacy permits.
- K. The board shall have the right to amend the notice of open applications prior to the deadline for submitting an application. Such amended notice shall be published in the same manner as the original notice of open applications.
- L. The board shall have the right to cancel a notice of open applications prior to the award of a marijuana pharmacy permit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1543 (August 2017), LR 49:1720 (October 2023).

#### §2447. Licensing Procedures

- A. Application for Initial Issuance of Permit
  - 1. The board shall develop an application form suitable for the marijuana pharmacy permit. The board may revise that application form on its own initiative in order to collect the information it deems necessary to properly evaluate an applicant.
  - 2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
  - 3. The applicant shall fully disclose the ownership of the entity that will own the permit as well as any additional holding companies that may exist, such that any natural person with any ownership interest shall be fully identified.
  - 4. In the event any person holding any ownership interest in the entity submitting an application for a marijuana pharmacy permit has engaged in any of the following activities, the entity shall be disqualified and the board shall not issue a marijuana pharmacy permit to that applicant:
    - a. within the two-year period preceding the date of the application, the person or any member of the person's immediate family served as a member of the board or its staff.
  - 5. The applicant shall provide a complete street address reflecting the location at which the applicant proposes to operate the marijuana pharmacy.
  - 6. The applicant shall provide the following information and records in the application process:
    - a. a detailed description of any other services or products to be offered by the marijuana pharmacy;
    - b. details regarding the applicant's plans to maintain adequate control against the diversion, theft, or loss of marijuana;

- documents or information sufficient to establish the applicant is authorized to conduct business in Louisiana and that all applicable state and local building, fire and zoning requirements, and local ordinances will be met;
- text and graphic materials showing the exterior appearance of the proposed marijuana pharmacy and its site compatibility with commercial or residential structures already constructed or under construction within the immediate neighborhood;
- e. repealed.
- f. such other documents and information reasonably required by the board to determine the applicant's suitability for permitting or to protect the public's health and safety.
- 7. The owner's managing officer and the pharmacist-in-charge shall be fully identified within the application and they both shall sign and date the application form.
- 8. The applicant shall direct the following persons to submit to the criminal history record check process used by the board, at the applicant's expense:
  - a. the owner's managing officer;
  - b. the pharmacist-in-charge; and
  - c. any person holding any share of ownership in the entity; provided however that any person not holding any share of ownership but holding a corporate officer position in the entity may be required to submit to the criminal history record check.
- 9. The requirement for a criminal history record check may be waived by the board in the event the person has already completed that process for the board within the two-year period prior to the date of the application.
- 10. Repealed.
- 11. In the event any information contained in the application or accompanying documents changes after being submitted to the board, the applicant shall immediately notify the board in writing and provide corrected information in a timely manner so as not to disrupt the application processing or permit selection process.
- 12. Repealed.
- 13. The application shall be accompanied by payment of the permit fees and administrative hearing fee authorized by LAC 46:LIII.115 and R.S. 40:1013.
- 14. When the staff has determined an entity's application package is complete, the application shall be referred to the board's application review committee, and further, the applicant shall be properly notified at least 30 days prior to the committee's hearing during which their application will be considered.
- 15. During the hearing held by the board's application review committee, the members shall consider, but are not limited to, the following criteria when evaluating an application for a marijuana pharmacy permit:
  - a. the character and fitness of the owner's managing officer, the pharmacist-in-charge, any of the owners and any other person who may have control or influence over the operation of the proposed marijuana pharmacy;
  - b. the location for the proposed marijuana pharmacy including, but not limited to:
    - i. its proximity to previously approved marijuana pharmacies or locations of proposed marijuana pharmacies with pending applications;
    - ii. whether the patient population in the area proposed by the marijuana pharmacy permit applicant justifies the need for a marijuana pharmacy, or an additional marijuana pharmacy, in that area;
    - iii. whether the proximity of the proposed marijuana pharmacy will have a detrimental effect upon any place used primarily for religious worship, public or private school, convent, charitable institution, whether supported by private or public funds, hospital or veterans' home or any camp or military establishment; or
    - iv. whether the number of marijuana pharmacies in the locality is such that the granting of a permit is detrimental to the public interest. In reaching a conclusion in this respect, the board may consider the population of, the number of like permits and number of all permits existent in, the particular municipality and the immediate neighborhood concerned, the effect that a new permit may have on such town or neighborhood or on like permits existent in such municipality or neighborhood.
  - c. the applicant's ability to maintain adequate control against the diversion, theft and loss of marijuana;
  - d. the applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls and ethics to ensure optimal safety and accuracy in the dispensing and sale of marijuana; and
  - e. the extent to which the applicant or any of the applicant's owners have a financial interest in any other permittee, licensee, registrant, or other applicant currently or previously credentialed by the board; and
  - f. any other reason provided by any federal law or rule or state law or rule that is not inconsistent with R.S. 40:1046 or 40:1047 or this Subchapter.

- 16. Following their evaluation of the applications for a marijuana pharmacy permit, the committee shall develop a recommendation for presentation to the board at the board's next meeting. The board may accept the committee's recommendation, select an alternative applicant, reject all of the applicants, or return all the applicants to the committee for their reconsideration.
- 17. The board may disqualify any applicant who:
  - a. submits an incomplete, false, inaccurate, or misleading application;
  - b. fails to submit an application by the published deadline; or
  - e. fails to pay all applicable fees.
- 18. The decision of the board to award or not to award a marijuana pharmacy permit to an applicant shall be final.
- 19. Upon the approval of an application, the board shall award the marijuana pharmacy permit and state controlled dangerous substance license to the applicant. Upon completion of a satisfactory inspection of the premises, the board shall issue the marijuana pharmacy permit and state controlled dangerous substance license to the applicant awarded the permit.
- 20. If an applicant has been awarded a marijuana pharmacy permit and has not commenced operation of such pharmacy within 310 days of being notified of the marijuana pharmacy permit award, the board may, in the board's discretion, rescind such marijuana pharmacy permit, unless such delay was caused by *force majeure*. A marijuana pharmacy shall be deemed to have commenced operation if the pharmacy is capable of operating in accordance with the applicant's approved application. In the event a marijuana pharmacy permit is rescinded pursuant to this Subsection, the board shall award a marijuana pharmacy permit by selecting among the qualified applicants who applied for the marijuana pharmacy permit that was rescinded. If no other qualified applicant applied for such marijuana pharmacy permit or satisfied the criteria for awarding a permit, the board shall publish, in accordance with this Section, a notice of open applications for marijuana pharmacy permits.
- B. Application for Renewal of Permit
  - 1. All marijuana pharmacy permits expire at midnight on December 31 of every year, regardless of the date of its initial issuance.
  - 2. The owner's managing officer and pharmacist-in-charge of the marijuana pharmacy permit shall complete, sign and date a permit renewal application form supplied by the board, and further, shall include all information requested on the form and attach the pharmacy permit renewal fee and state controlled dangerous substance license renewal fee authorized in LAC 46:LIII.115 and the prescription monitoring program fee authorized in R.S. 40:1013, and further, shall submit the renewal application package to the board office prior to the expiration date of the pharmacy permit.
  - 3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
  - 4. In the event the pharmacy does not submit a properly completed renewal application form and fee to the board prior to the expiration of the permit, the permit shall be rendered null and void. A marijuana pharmacy shall not operate with an expired permit. Evidence it has done so will provide sufficient basis for the board to discipline the permit for violation of R.S. 37:1241(A)(12).
  - 5. An application for the late renewal of an expired (lapsed) marijuana pharmacy permit that is received in the board office no later 30 days after the expiration date of the permit may be processed by the board staff, provided the appropriate delinquent fee authorized in LAC 46:LIII.115 is included with the application.
  - 6. A marijuana pharmacy permit not renewed by 30 days after the expiration date shall be automatically terminated by the board.
  - 7. An application for the reinstatement of a terminated marijuana pharmacy permit shall be referred to the board's reinstatement committee for its consideration.
- C. Application for Reinstatement of Terminated, Suspended, or Revoked Marijuana Pharmacy Permits
  - 1. The applicant shall complete an application form for this specific purpose supplied by the board; the application shall require the inclusion of the annual renewal fee, the delinquent fee, the administrative hearing fee, and the reinstatement fees authorized in LAC 46:LIII.115 and the program fee authorized in R.S. 40:1013.
  - 2. An application for the reinstatement of a marijuana pharmacy permit previously terminated, suspended or revoked by the board may only be approved following a preliminary hearing to determine whether the reinstatement of the permit is in the public's best interest.
- D. Maintenance of Marijuana Pharmacy Permit
  - 1. A marijuana pharmacy permit is valid only for the entity or person to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall the permit be valid for any premises other than the business location recorded thereon.

- 2. Repealed.
- 3. Prior to making any change in the marijuana pharmacy's name or trade name, the owner of the permit shall notify the board and request approval of the contemplated name or trade name. The board shall reasonably accommodate such requests, unless there is cause not to do so (e.g., duplicative or misleading names). The marijuana pharmacy shall not change its name or trade name until approved by the board.
- 4. Prior to any modification, remodeling, expansion, reduction, other physical, non-cosmetic alteration of the marijuana pharmacy, the owner of the permit shall notify the board and request approval of the contemplated change(s). The board shall reasonably accommodate such request, unless there is cause not to do so (e.g., inconsistent with operating requirements). The marijuana pharmacy shall not make such changes until approved by the board.
- 5. Prior to any change in the location of a marijuana pharmacy, the owner of the permit shall submit an application form for that purpose supplied by the board and pay the appropriate fee authorized in LAC 46:LIII.115. The board may require an inspection of the new location prior to the issuance of the permit for the new location. No marijuana pharmacy shall commence operation in a new location until approved by the board.
- 6. The owner of the pharmacy permit shall notify the board no later than 30 days following a change in the pharmacist-in-charge for the marijuana pharmacy permit.
- 7. The owner of the pharmacy permit shall notify the board no later than 30 days following a change in the owner's managing officer for the marijuana pharmacy permit.
- 8. In the event a marijuana pharmacy contemplates permanent closure, the pharmacist-in-charge shall notify the board in accordance with the rules governing the permanent closure of a pharmacy as described in Chapter 11 of this Part.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1544 (August 2017), amended LR 46:577 (April 2020), LR 48:2102 (August 2022), LR 49:1720 (October 2023).

# §2449. Marijuana Pharmacy Personnel

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1546 (August 2017), amended LR 48:2103 (August 2022), repealed LR 49:1720 (October 2023).

## §2451. Operation of Marijuana Pharmacy

- A. No person may operate a marijuana pharmacy without a marijuana pharmacy permit issued by the board, and further, that permit shall be in active or restricted status. A pharmacist shall be on duty at all times during the regular open hours of the marijuana pharmacy.
- B. A marijuana pharmacy shall not dispense marijuana from, obtain marijuana from, or transfer marijuana to, a location outside of the state of Louisiana.
- C. A marijuana pharmacy shall not obtain, cultivate, deliver, transfer, transport, sell or dispense marijuana except:
  - 1. it may acquire marijuana from an authorized producer pursuant to the provisions of R.S. 40:1046; and
  - 2. it may dispense and sell marijuana to a patient with a recommendation/prescription/order for such marijuana or the patient's caregiver.
- D. No person at a marijuana pharmacy shall provide marijuana samples.
- E. A marijuana pharmacy shall sell marijuana products only in a secure and light-resistant container. Nothing herein shall preclude a pharmacist from compounding a marijuana product appropriate for his patient.
- F. Only a pharmacist may dispense marijuana, however, other licensed pharmacy personnel may assist the pharmacist in the dispensing process. The sale of dispensed marijuana products may be accomplished by any pharmacy employee.
- G. A marijuana pharmacy shall place all products sold to the patient or caregiver in an opaque package that shall not indicate the contents of the package, the originating facility or in any other way cause another person to believe that the package may contain marijuana.
- H. A marijuana pharmacy shall not permit any person to enter the prescription department unless that person's responsibilities necessitate access to the department and then for only as long as necessary to perform the person's job duties.
- I. While inside the pharmacy, all pharmacy employees shall wear name tags or similar forms of identification that clearly identify them to the public, including their position at the pharmacy.

- J. A marijuana pharmacy shall be open for qualifying patients and primary caregivers to purchase marijuana products for a minimum of 10 hours per week.
  - A marijuana pharmacy that closes during its normal hours of operation shall implement procedures to
    notify patients and caregivers of when the marijuana pharmacy will resume normal hours of operation.
    Such procedures may include, but are not limited to, telephone system messages and conspicuously
    posted signs.
  - 2. In the event the pharmacist on duty leaves the prescription department, the prescription department shall comply with the provisions of §1109 (temporary absence) or §1111 (closure) of this Part.
- K. A marijuana pharmacy shall provide information to patients and caregivers regarding the possession and use of marijuana. Such informational material shall include information related to:
  - 1. limitations on the right to possess and use marijuana pursuant to R.S. 40:1046;
  - 2. safe techniques for proper use of marijuana and paraphernalia;
  - 3. alternative methods and forms of consumption by which one can use marijuana;
  - 4. signs and symptoms of substance abuse; and
  - 5. opportunities to participate in substance abuse programs.
- L. Repealed.
- M. The receipt of all deliveries from producers shall be carried out under the direct supervision of a pharmacist who shall be present to accept the delivery.
- N. No marijuana pharmacy shall acquire, possess or dispense any controlled substance other than medical marijuana products authorized by <u>R.S. 40:1046</u>.
- O. No marijuana shall be administered on the premises of a marijuana pharmacy, except during patient counseling, education or training.
- P. No person associated with a marijuana pharmacy shall enter into any agreement with an authorized clinician or health care facility concerning the provision of services or equipment that may adversely affect any person's freedom to choose the marijuana pharmacy at which the patient or caregiver will purchase marijuana.
- Q. Delivery of Dispensed Marijuana Products.
  - 1. A marijuana pharmacy shall dispense a marijuana product to a patient or his caregiver in the marijuana pharmacy. At the patient's request, the caregiver may deliver a dispensed marijuana product to the patient's location.
  - 2. Each marijuana pharmacy shall offer home delivery to patients in each zip code within its region at least once per month.
  - 3. At the patient's request, the marijuana pharmacy may deliver or facilitate the delivery of a dispensed marijuana product to the patient's location.
  - 4. The delivery of a dispensed marijuana product is subject to the following requirements:
    - a. The marijuana pharmacy shall not deliver or facilitate the delivery of a marijuana product to a location outside the state.
    - b. The marijuana pharmacy shall ensure the physical integrity and security of the marijuana product while in transit.
    - c. In the event the delivery of the marijuana product is not completed, the marijuana product shall be returned to the marijuana pharmacy from which it was dispensed.
    - d. In the event the pharmacist-in-charge of the marijuana pharmacy cannot assure the integrity and security of a returned marijuana product, the pharmacy shall dispose of the marijuana product.
- R. No marijuana shall be sold when the marijuana pharmacy is closed and not open for business.
- S. Board representatives, local law enforcement or other state or local government officials may enter any area of a marijuana pharmacy if necessary to perform their governmental duties.
- T. Right of inspection. The board, or its agent, representative, or designee, is authorized:
  - 1. to enter a marijuana pharmacy at any time during its hours of operation, or any other place, including a vehicle, wherein marijuana is held, dispensed, sold, or otherwise disposed of;
  - 2. to inspect within reasonable limits and in a reasonable manner, such place and all pertinent equipment, finished and unfinished material, containers and labeling, and all things therein, including records, files, financial data, sales data, shipping data, pricing data, employee data, research, papers, processes, controls and facilities; and
  - 3. to inventory any stock of marijuana therein and obtain samples of any marijuana or marijuana product, any labels or containers for marijuana, paraphernalia, and of any finished and unfinished material.
- U. Inspection of records. Every person required to prepare, obtain or keep records, logs, reports or other documents, and every person in charge, or having custody, of such documents shall maintain such documents in an auditable format for no less than two years. Upon request, such person shall make such documents immediately available for inspection and copying by the board or its authorized representative. In complying

with this Section, no person shall use a foreign language or codes or symbols to designate marijuana types or persons in the keeping of any required document.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1547 (August 2017), amended LR 46:1227 (September 2020), LR 47:590 (May 2021), LR 48:2103 (August 2022), LR 49:1720 (October 2023).

# §2453. Security Requirements for Marijuana Pharmacies

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1548 (August 2017), amended LR 48:1903 (July 2022), repealed LR 49:1721 (October 2023).

# §2455. Reportable Security Events

- A. Upon becoming aware of discrepancies identified during inventory, diversion, theft, loss, or unauthorized destruction of any marijuana, or of any loss or unauthorized alternation of records related to marijuana or patients, a pharmacy shall immediately notify:
  - 1. appropriate law enforcement authorities; and
  - 2. the board.
- B. A pharmacy shall provide the written notice to the board by way of a signed statement which details the circumstances of the event, including an accurate inventory of the quantity and brand names of the marijuana diverted, stolen, lost, destroyed, or damaged, along with confirmation that the local law enforcement authorities were notified. A pharmacy shall make such notice no later than 24 hours after discovery of the event.
- C. Repealed.
- D. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1550 (August 2017), amended LR 49:1721 (October 2023).

# §2457. Standards of Practice

- A. Environmental Standards
  - 1. The prescription department shall be of sufficient size commensurate with the nature and scope of practice. The space occupied by the prescription department shall be restricted to authorized personnel only, as determined by the pharmacist-in-charge, and shall not be accessible to the general public. A marijuana pharmacy shall not permit any person less than eighteen years of age to enter the prescription department, with the exception of patients being counseled by the pharmacist.
  - 2. The prescription department shall contain sufficient fixtures, equipment, and supplies commensurate with the nature and scope of practice for that pharmacy.
  - 3. The prescription department shall include a sink with a hot and cold water supply, exclusive of restroom facilities, with approved sewage disposal.
  - 4. All areas where drugs and devices are stored shall be dry, well-lighted, well-ventilated, and maintained at temperatures which will ensure the integrity of drugs during their storage and prior to their dispensing as stipulated by the *United States Pharmacopeia* and/or manufacturer's or distributor's product labeling unless otherwise indicated by the board.
  - 5. The prescription department shall be secured by one or more physical barriers with suitable locks and a monitored alarm system capable of detecting unauthorized entry.
  - 6. Prescription and other patient healthcare information shall be maintained in a manner that protects the integrity and confidentiality of such information.
- B. Minimum Staffing Requirements
  - 1. There shall be at least one pharmacist on duty at all times the pharmacy is open for business.
  - 2. Every pharmacist practicing in the pharmacy shall possess a Louisiana pharmacist license in active status as well as access privileges to the state prescription monitoring program.
  - 3. A pharmacy intern, pharmacy technician or pharmacy technician candidate may assist the pharmacist in the prescription department, but only when in possession of valid credentials issued by the board. The supervising pharmacist may establish a delegate credential in the state prescription monitoring program for any licensed pharmacy personnel affiliated with that pharmacy.

- 4. Additional clerical personnel may also be present at the pharmacy.
- 5. No person shall be employed by, or affiliated with, a marijuana pharmacy prior to their eighteenth birthday.

## C. Operational Standards

- 1. The marijuana pharmacy shall comply with the provisions of Chapters 11, 25, 27, 29, and 31 of this Part except when this Subchapter grants exceptions or imposes more stringent requirements.
- 2. In the event the marijuana pharmacy intends to close permanently, the pharmacist-in-charge (PIC) shall comply with the pharmacy closure procedures described in Chapter 11 of this Part, and further, the owner of the pharmacy permit shall not prevent or interfere with the PIC's performance of those tasks.
  - a. In addition to the other closure requirements, the closing pharmacy shall include in its notice to the board and to the public the identification of the destination pharmacy where the closing pharmacy's prescription records will be transferred. That destination pharmacy shall be the marijuana pharmacy nearest the closing pharmacy, unless otherwise approved by the board.

## D. Recordkeeping Requirements

- 1. When the pharmacy receives a request for marijuana from a recommending authorized clinician in written form, the pharmacist shall cause the form to be scanned and filed using an electronic imaging system in compliance with Section 1123 of this Part.
- 2. Request forms (and electronic images thereof) shall be retained on the pharmacy's premises for at least two years after the date of dispensing, and further, shall be readily retrievable upon request by the board.
- 3. Inventory of Marijuana Product
  - a. The pharmacist-in-charge shall develop and maintain a perpetual inventory of all marijuana products acquired, held, dispensed, and disposed by the pharmacy.
  - b. The pharmacy shall access the LMMTS and enter all acquisitions and product transfer transactions in that system.
  - c. In the event the pharmacist-in-charge designates an agent to retrieve new marijuana product inventory from the production facility, the pharmacist shall verify the agent is at least 21 years of age and is eligible to drive on public roadways.
  - d. The pharmacist-in-charge shall conduct an annual inventory of all marijuana products in the possession of the pharmacy on any date which is within one year of the previous annual inventory, and further, shall conduct additional inventory counts on the following occasions:
    - i. arrival of a new pharmacist-in-charge;
    - ii. discovery of any significant loss, disappearance, or theft of marijuana product;
    - iii. departure of a pharmacist-in-charge; and
    - iv. permanent closure of the pharmacy.
  - e. Inventory records shall be retained on the pharmacy's premises for at least two years after the most recent entry.
- 4. The pharmacy shall develop and maintain sufficient records to fully reveal the business transactions related to marijuana products, including their procurement and sale, for the current tax year as well as the two immediately preceding tax years, all of which shall be made available to the board upon request.
- 5. The board may require any pharmacy or its owners to furnish such information as the board considers necessary for the proper administration of <u>R.S. 40:1046</u>, and may require a financial audit of the business of any marijuana pharmacy, and the expense thereof shall be paid by the marijuana pharmacy.

#### E. Professional Practice Standards

- 1. Recommendation / Opinion (hereinafter, "request") for Therapeutic Marijuana
  - a. The pharmacist may accept any request for a marijuana product which has been:
    - i. issued by an authorized clinician in possession of a current and unrestricted license to practice in this state as well as a current and unrestricted state controlled substance license with therapeutic marijuana privileges from the board; and
    - ii. received directly from the authorized clinician and not from the patient or any third party other than the entity transmitting the request, either by electronic means conforming with the provisions of 21 CFR 1311 or its successor, or in the alternative, by facsimile bearing a handwritten or digital signature of the authorized clinician.
  - b. The request shall disclose the following information at a minimum:
    - i. name, address, telephone number, and national provider identifier (NPI) number of the authorized clinician issuing the request;
    - ii. name, address, and date of birth (or age) of the patient for whom the request was issued;
    - iii. identification of the debilitating medical condition for which the treatment has been requested;
    - iv. type of marijuana product requested;
    - v. date request was issued;

- vi. self-certification the authorized clinician holds a current and unrestricted license to practice in this state; and
- vii. signature of the authorized clinician issuing the recommendation, excluding any proxy or agent.
- c. Requests for marijuana products shall expire one year after the date of issue, unless a shorter period of time is indicated by the authorized clinician. A pharmacist shall not dispense marijuana product pursuant to an expired request.
- d. Requests for raw or crude marijuana products intended for persons under 21 years of age shall specifically indicate a recommendation for raw or crude forms of marijuana for such persons.
- e. A marijuana pharmacy shall transfer an unexpired request for marijuana product to another marijuana pharmacy when requested by the patient or his caregiver.
- 2. Upon request by the patient or caregiver and prior to dispensing any marijuana product to a patient, the pharmacist shall provide product testing results available to the pharmacist for the product contemplated for dispensing.
- 3. Dispensing Marijuana Products
  - a. Prior to dispensing any marijuana product to a patient, the pharmacist shall review the patient's records in the state prescription monitoring program. The pharmacist shall resolve any concerns identified in that review by consultation with the recommending authorized clinician.
  - b. Dispensing Limitations
    - i. A pharmacist shall not dispense more than two and one-half ounces, or 71 grams, of raw or crude marijuana every 14 days to any person.
    - ii. Subject to the above limitation on dispensing raw or crude marijuana products, a pharmacist may dispense marijuana products on multiple occasions as indicated by the authorized clinician and needed by the patient until the request expires; however, the pharmacist shall not dispense more than a 90-day supply of marijuana product at one time nor more than a one-year supply pursuant to a single request.
  - c. Dispensing Marijuana Products to Visiting Qualifying Patients
    - i. A visiting qualifying patient may obtain medical marijuana from a marijuana pharmacy, subject to the dispensing limitations of Subparagraph 3.b of this Subsection, upon producing evidence of his valid medical marijuana registry identification card, or its equivalent, which has been issued under the medical marijuana laws of another state, district, territory, commonwealth, or insular possession of the United States and in compliance with R.S. 40:1046.1.
    - ii. A pharmacist may dispense medical marijuana to a visiting qualifying patient, subject to the dispensing limitations of Subparagraph 3.b of this Subsection, upon obtaining evidence of his valid medical marijuana registry identification card, or its equivalent, which has been issued under the medical marijuana laws of another state, district, territory, commonwealth, or insular possession of the United States and in compliance with R.S. 40:1046.1.
- 4. Labeling of Marijuana Product Dispensed
  - a. The pharmacist shall not dispense any marijuana product that does not bear the producer label required by the LDH, and further, the pharmacy dispensing label shall not overlay or obscure the producer label in any way.
  - b. The pharmacy's dispensing label shall contain, at a minimum, the following data elements:
    - i. name and address of the pharmacy dispensing the product;
    - ii. telephone number or other contact information of the pharmacy dispensing the product;
    - iii. name of the recommending authorized clinician;
    - iv. name of the patient;
    - v. date the product was dispensed;
    - vi. prescription number, which shall be a unique identifier for that specific transaction;
    - vii. name of the marijuana product, including any concentration, strength, or other identifiers of the marijuana product;
    - viii. quantity of marijuana dispensed;
    - ix. directions for use of the product;
    - x. expiration date of the product, which shall not exceed the expiration date determined by the producer of the product; and
    - xi. other information selected by the dispensing pharmacist to inform the patient as to the best use of the product for the intended purpose.
- 5. The pharmacist shall comply with the rules on drug utilization review and patient counseling in Chapter 5 of this Part.

- 6. Reporting transactions to state prescription monitoring program. The pharmacy shall comply with the reporting requirements as found in Chapter 29 of this Part.
- 7. Disposal of Marijuana Product.
  - A pharmacy may refuse to accept the delivery of marijuana product from a producer when it is determined to be misbranded, adulterated, expired, deteriorated, undesired, excess, unauthorized, or unfit for dispensing.
  - b. When the pharmacist determines a marijuana product is no longer suitable for dispensing, the product shall be removed from active dispensing stock and quarantined in the pharmacy pending its disposal.
  - c. The pharmacist-in-charge shall render the waste unusable by grinding and incorporating the waste with other ground materials so the resulting mixture is at least 50 percent non-marijuana waste by volume. Material used to grand with the waste may include:
    - i. yard waste;
    - ii paper waste;
    - iii. cardboard waste;
    - iv. plastic waste; or
    - v. soil or sand.
  - d. Waste shall be rendered unusable prior to leaving the pharmacy. Waste rendered unusable shall be disposed of by delivery to an approved solid waste facility for final disposition.
    - i. Examples of acceptable permitted solid waste facilities include:
      - (a) compost; anaerobic digester;
      - (b) landfill, incinerator; or
      - (c) waste-to-energy facility.
  - e. The pharmacist-in-charge shall prepare a record of each disposal, and that record shall contain, at a minimum, the following information:
    - i. brand name and other specific identifiers of the marijuana product disposed;
    - ii. quantity of product disposed;
    - iii. manner of disposal; and
    - iv. signatures of the pharmacist-in-charge disposing the product plus at least one witness who is either a credentialed staff member of that pharmacy or an agent of the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1550 (August 2017), amended LR 45:1473 (October 2019), LR 47:246 (February 2021), LR 47:1111 (August 2021), LR 48:1903 (July 2022), LR 48:2103 (August 2022), LR 49:1721 (October 2023).

# §2459. Advertising

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1046.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:1552 (August 2017), repealed LR 49:1722 (October 2023).

#### [End of Chapter 24]

# Chapter 25. Prescriptions, Drugs, and Devices

## Subchapter A. General Requirements

# §2501. Prescription Drugs and Devices

- A. Prescription Drugs or Devices. A prescription drug or device is a medication or mechanism that may only be dispensed by a pharmacist on the order of a licensed practitioner and shall bear the "Rx Only" notation or any other designation of similar import required by law on the label of a commercial container.
  - 1. Dispensing. Prescription drugs or devices shall be dispensed only by a Louisiana-licensed pharmacist.
  - 2. Possession. Prescription drugs or devices shall be procured and possessed in the course of the practice of pharmacy by a permitted pharmacy.
  - 3. Storage
    - a. Prescription drugs or devices shall be stored in a permitted pharmacy under the immediate control and responsibility of a pharmacist.
    - b. All areas where drugs are stored shall be maintained under environmental conditions which will ensure the integrity of the drug, as specified by the United States Pharmacopeia (USP) and/or manufacturer's or distributor's product information or labeling.

#### B. Misbranded Drugs

- 1. Misbranded drugs are:
  - a. those drugs whose labeling is false or misleading in any particular manner; or
  - b. those drugs whose label does not bear the name and address of the manufacturer, packer, or distributor, and does not have an accurate statement of the quantities of the active ingredients; or
  - c. those drugs without an accurate monograph; or
  - d. those drugs meeting the qualifications for misbranded drugs as noted in the <u>Federal Food, Drug, and</u> Cosmetic Act, or its successor.
- 2. It is unlawful to possess or dispense misbranded drugs.
- C. Adulterated Drugs
  - 1. Adulterated drugs are contaminated medicinal substances having deleterious foreign or injurious materials, which fail to meet safety, quality, and/or purity standards.
  - 2. It is unlawful to possess or dispense adulterated drugs.
- D. Expired Drugs. Expired drugs shall not be dispensed and shall be removed from the pharmacy drug inventory.
- E. Recalled Drugs. Recalled drugs shall be removed from the pharmacy inventory immediately upon notice. Recalls are classified as:
  - 1. Class I a situation in which there is a strong likelihood that the use of, or exposure to, a violative product will cause serious adverse health consequences or death;
  - 2. Class II a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote;
  - 3. Class III a situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2101 (October 2003), effective January 1, 2004, amended by Department of Health, Board of Pharmacy, LR 50:1156 (August 2024).

# §2503. Drug Returns; Drug Disposal

- A. Unless otherwise allowed by law, drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.
- B. When a patient or his designee wishes to return previously dispensed prescription drugs to a pharmacy for disposal, the pharmacy shall inform the patient or his designee of the disposal mechanisms available to him. In the event the pharmacy elects to accept such previously dispensed products for disposal, the pharmacy shall comply with the following requirements:
  - 1. From the time of receipt of such products until the time of disposal, the pharmacy shall quarantine such products to keep them separate from its active dispensing stock and shall take appropriate security measures to prevent the theft or diversion of such products.
  - 2. The pharmacy shall comply with the provisions of <u>21 CFR §1317</u> or its successor for the pharmacy's disposal of controlled substances and other non-hazardous waste pharmaceuticals.

 The pharmacy shall comply with the provisions of 40 CFR §261 or its successor for the pharmacy's disposal of hazardous waste pharmaceuticals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2101 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:973 (June 2020).

# §2505. Investigational Drugs

- A. The pharmacist shall conduct, participate in, and support medical and pharmaceutical research appropriate to the goals, objectives, and resources of the facility.
- B. The pharmacist shall ensure the development of policies and procedures for the appropriate use of investigational drugs; such policies shall be consistent with the applicable federal rules pertaining to investigational drugs.
  - 1. The use of investigational drugs shall be authorized by the principal investigator, or his authorized clinician.
  - 2. The pharmacist shall ensure the development of a central repository for the acquisition and maintenance of essential information and the dissemination of that information to all personnel tasked with procurement, storage, dispensing, or administration of investigational drugs.
  - 3. The pharmacist shall retain a copy of the research protocol in the pharmacy; the dispensing pharmacist shall review the protocol prior to dispensing the investigational drug.
  - 4. The dispensing label for investigational drugs shall comply with the provisions of this Chapter; in addition, the label shall bear the phrase "For Investigational Use Only" or a similar caution.
- C. The pharmacist shall store investigational drugs in the pharmacy separate from the active dispensing stock of approved drugs.
  - 1. The storage location shall be consistent with the environmental standards for temperature, humidity, and light indicated by the manufacturer.
  - 2. The storage location shall be secured against improper access or diversion.
- D. The pharmacist shall maintain a perpetual inventory record for each investigational drug, with such record to contain, at a minimum, the following data elements:
  - 1. drug's name, dosage form, strength, lot number, and expiration date;
  - 2. name, address, and telephone number of the study sponsor;
  - 3. protocol number;
  - 4. identification of the dispensing pharmacist; and
  - 5. disposition of any remaining drug supply.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2101 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:575 (April 2020).

#### §2507. Veterinary Prescription Drugs

- A. Veterinary prescription drugs are prescription medications for animal use prescribed by a licensed veterinarian pursuant to a valid veterinarian-client-patient relationship and dispensed by a licensed pharmacist to the veterinarian's client, for a legitimate medical purpose, that are unsafe for unsupervised use as defined in 21 CFR §201.105, or its successor.
- B. Dispensing Requirements. Veterinary prescription drugs shall be exclusively dispensed by a duly licensed pharmacist upon the order of a licensed veterinarian, unless otherwise provided by law.
- C. Labeling Requirements. Veterinary prescription drugs shall be dispensed in an appropriate container, and in addition to the labeling requirements in Chapter 11 of this Part, shall contain the following information:
  - 1. the commercial label inscription "Caution: Federal law restricts this drug tot use by or on the order of a licensed veterinarian"; and
  - 2. the client's name and patient's animal species.
- D. Prescription Form Requirements. Prescriptions issued by a licensed veterinarian shall conform to Section 2511 of this Chapter.
- E. Storage. Veterinary prescription drugs shall be maintained in the prescription department of a pharmacy, and shall be kept separate and apart from drugs intended for human use.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2107 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:585 (April 2020).

# §2509. Prescription Devices

- A. In the interest of public health, safety, and welfare, the board may, from time to time, restrict the sale of certain devices to be dispensed only by a licensed pharmacist after a legitimate medical need has been demonstrated. A legitimate medical need includes the prevention of the transmission of communicable diseases.
- B. Pharmacy Device. A pharmacy device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component 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 other designation of similar import.
  - 1. Hypodermic Apparatus. Hypodermic means any syringe, needle, instrument, device, or implement intended or capable of being adopted for the purpose of administering drugs by subcutaneous, intramuscular, or intravenous injection.
    - a. Sale. Hypodermic syringes and/or needles shall be sold or distributed only by a licensed pharmacist, physician, dentist, veterinarian, podiatrist, embalmer, drug wholesaler, surgical supplier, or other legally authorized distributor.
    - b. Storage. Hypodermic syringes and/or needles shall be stored in the prescription department or in another secure area.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2107 (October 2003), effective January 1, 2004.

# Subchapter B. Prescriptions

# §2511. Prescriptions and Chart Orders

A. Definitions. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section:

Chart Order – a lawful order entered on the electronic or paper chart or medical record of an inpatient or resident of an institutional facility by a practitioner or his licensed healthcare designee for a drug or device and shall be considered a prescription drug order provided it contains the following:

- 1. full name of the patient;
- 2. date of issuance;
- 3. name, strength, and dosage form of the drug prescribed;
- 4. directions for use;
- 5. name of the prescribing practitioner;
- 6. the prescribing practitioner's written or electronic signature or the written or electronic signature of the practitioner's licensed healthcare designee, who shall be a licensed nurse, pharmacist, or physician practicing in a long-term care facility. The licensed healthcare designee shall be authorized to document a chart order in the patient's medical record on behalf of the prescribing practitioner pending the prescribing practitioner's signature, or to communicate a prescription to a pharmacy whether telephonically, by facsimile transmission, or electronically.

*Electronic Prescription* – a prescription generated, signed, and transmitted in electronic form, excluding electronically transmitted facsimile documents.

Practice Affiliation – repealed.

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

*Prescription or Prescription Drug Order* – 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.

- B. Patient Authority to Acquire Prescription Drug or Device
  - A prescription or chart order represents the lawful authority for a patient, or his agent or caregiver, to acquire a prescription drug or device from a pharmacy licensed to dispense prescription drugs and devices.
  - 2. In the absence of refill instructions on the original prescription, the prescription shall not be refilled. A pharmacist, using his professional judgment, may dispense the total quantity authorized in one transaction, or in the alternative, may dispense partial quantities in multiple transactions, provided

- however, that the sum of the partial quantities shall not exceed the total quantity authorized.
- 3. In the event a prescription contains refill instructions, the prescription may be refilled when requested by the patient, or his agent or caregiver. A pharmacist, using his professional judgment, may dispense the quantity authorized for each refill in a single transaction, or in the alternative, may dispense partial quantities in multiple transactions, provided however that the sum of the partial quantities shall not exceed the total quantity authorized.
- 4. While the documentation of a prescription or chart order shall be retained by the dispensing pharmacy as evidence of its lawful dispensing of the prescription drug, the patient's lawful authority to obtain the drug conveyed by the prescription or chart order shall continue to exist until the earliest of the expiration date of the prescription or chart order, or in the alternative, when the total quantity authorized has been dispensed.
- 5. In the event a patient, or his agent or caregiver, requests a pharmacy to transfer an unfilled prescription for a medication not listed as a controlled substance to another pharmacy, the pharmacy shall comply with that request as soon as possible, but no later than the end of the next business day.
- 6. In the event a patient, or his agent or caregiver, requests a pharmacy to transfer the remainder of an unexpired prescription to another pharmacy, the pharmacy shall transfer that prescription information in compliance with the provisions of this Chapter as soon as possible but no later than the end of the next business day. Prior to such transfer, a pharmacy shall not cancel the remainder of an unexpired prescription unless such action is required by law or rule or is requested by the prescriber.

# C. Persons Authorized to Issue Prescriptions and Chart Orders

- 1. A prescription for a drug or device may be issued by a practitioner with valid prescriptive authority.
- 2. A prescription may be prepared by the agent of the prescriber for the signature of the prescriber, but the prescriber retains accountability for the proper issuance of a valid prescription. A prescriber's agent may communicate a valid prescription to a pharmacy.
- 3. A pharmacist may issue a prescription when so authorized by law, rule, standing order, or practice agreement.

## D. Required Information

- 1. A prescription shall contain the following data elements:
  - a. prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, the Drug Enforcement Administration (DEA) registration number;
  - b. patient's name, and if for a controlled substance, address;
  - c. date prescription issued by the prescriber;
  - d. name of drug or device, and if applicable, strength, and quantity to be dispensed;
  - e. directions for use;
  - f. signature of the prescriber; and
  - g. refill instructions, if any. In the absence of refill instructions on the original prescription, the prescription shall not be refilled.
- 2. In the event a pharmacist receives a prescription or chart order lacking certain required information, the pharmacist, pharmacy intern, or certified pharmacy technician may consult with the prescriber or his agent to clarify the prescriber's intent.

#### E. Manner of Issuance

- 1. Oral Prescriptions
  - a. Upon the receipt of an oral prescription from an authorized prescriber, the pharmacist or pharmacy intern or pharmacy technician shall reduce the order to a written form prior to dispensing the medication. As an alternative to recording such prescriptions on paper forms, a pharmacist may enter the prescription information directly into the pharmacy's dispensing information system.
  - b. In the event a pharmacy intern or pharmacy technician transcribes such a prescription, the supervising pharmacist shall initial or countersign the prescription form prior to processing the prescription.
- 2. Written Prescriptions. A written prescription shall conform to the following format:
  - a. The prescription form shall be of a size not less than 4 inches by 5 inches, and shall bear a single printed signature line.
  - b. The prescription form shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, the Drug Enforcement Administration (DEA) registration number. In the event that multiple practitioners are identified on the prescription form, the authorizing prescriber's specific identity shall be clear and unambiguous. This identification may be indicated by any means, including but not limited to, a marked check box next to, or circling, the authorized prescriber's printed name.

- c. No prescription form shall contain more than four active prescription drug orders. Each active prescription drug order on the form shall provide the following:
  - i. check box labeled "Dispense as Written", or "DAW", or both; and
  - ii. the number of refills, if any.
- d. The prescription shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner on the date issued and in the same manner as he would sign a check or legal document (e.g., J. H. Smith or John H. Smith). Examples of invalid signatures include rubber stamps, signatures of anyone other than the prescriber, and computer generated signatures.
- e. Receipt via Facsimile
  - i. Pharmacies may elect to receive written prescriptions via a facsimile machine located within the prescription department. The paper used to print such prescriptions shall produce a non-fading image. The pharmacy may elect to scan such documents in compliance with the provisions of §1123 of this Part.
  - ii. Pharmacies may elect to receive written prescriptions via electronic facsimile directly within their pharmacy information system. The pharmacy shall retain such records in compliance with §1123 of this Part.
- f. Chart orders and forms used by pharmacists to record telephoned or transferred prescriptions are exempt from the format requirements listed in this Section.
- 3. Electronic Prescriptions
  - a. The prescription shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, the DEA registration number.

#### F. Prescription Adaptation

- 1. With the consent of the patient, or his agent or caregiver, a pharmacist may adapt a prescription drug order or chart order unless the prescriber has indicated adaptation is not permitted, subject to the following limitations:
  - a. A pharmacist may change the quantity of medication prescribed if:
    - i. the prescribed quantity or package size is not commercially available;
    - ii. the change in quantity is related to a change in the dosage form;
    - iii. the change is intended to dispense up to the total amount authorized by the prescriber; or
    - iv. the change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program.
  - b. A pharmacist may change the dosage form of the medication prescribed if it is in the best interest of the patient care; however, the pharmacist shall modify the prescriber's directions to ensure an equivalent amount of the medication prescribed is dispensed.
  - c. A pharmacist may add information missing on the prescription drug order or chart order if there is evidence to support the change.
- 2. A pharmacist who adapts a prescription drug order or chart order shall document the adaptation in the patient's record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2102 (October 2003), effective January 1, 2004, LR 41:98 (January 2015), LR 41:2147 (October 2015), amended by the Department of Health, Board of Pharmacy, LR 43:2162 (November 2017), LR 46:585 (April 2020), LR 47:1644 (November 2021), LR 49:1722 (October 2023).

# §2513. Prescription Receipt and Verification of Prescription Drug Orders and Chart Orders

- A. The receiving pharmacist is responsible for verification of the authenticity of the prescription.
- B. The dispensing pharmacist is responsible for the accuracy of the medications or devices dispensed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2103 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:585 (April 2020), LR 47:1644 (November 2021).

# §2515. Prescriptions Based Upon Electronic Questionnaires

A. A prescription issued solely on the results of answers to an electronic questionnaire, in the absence of a

- documented patient evaluation including a physical examination, is issued outside the context of a valid physician-patient relationship, and is not a valid prescription.
- B. If a pharmacist has reasons to suspect that a prescription was authorized solely on the results of an electronic questionnaire and in the absence of a documented patient evaluation including a physical examination, the pharmacist shall ascertain if that practitioner's standard of practice allows that practitioner to authorize a prescription under such circumstances. Reasons to suspect that a prescription may have been authorized in the absence of a valid physician-patient relationship, or in violation of the practitioner's standard of practice, include:
  - 1. the number of prescriptions authorized on a daily basis by the practitioner;
  - 2. the manner in which the prescriptions are authorized by the practitioner or received by the pharmacy, i.e., electronically;
  - 3. the geographical distance between the practitioner and the patient(s);
  - 4. knowledge by the pharmacist that the prescription was issued solely as a result of answers to an electronic questionnaire; or
  - 5. knowledge by the pharmacist that the pharmacy he works for directly or indirectly participates in an internet site that markets prescription drugs to the public.
- C. A pharmacist who has reasons to suspect that a prescription may have been authorized in the absence of a valid physician-patient relationship, or otherwise in violation of the prescriber's standard of practice, shall not fill such prescription until he has obtained proof to a reasonable certainty of the validity of such prescription.
- D. A pharmacist who dispenses prescription drugs in violation of this Section is not acting in the best interest of the patient and is dispensing outside the course of the professional practice of pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2103 (October 2003), effective January 1, 2004.

# §2517. Prescription Dispensing; Equivalent Drug Product Interchange; Drug Returns; Drug Disposal

- A. Prescription dispensing means the issuance, by a licensed pharmacist, of one or more doses of medication in a suitable container, properly labeled for subsequent administration, and shall consist of the following procedures or practices:
  - 1. receiving and interpretation of the prescription order;
  - 2. assembling the drug products and an appropriate container;
  - 3. preparing the prescription by compounding, mixing, counting, or pouring;
  - 4. affixing the proper label to the final container;
  - 5. patient counseling as required; and
  - 6. transfer of possession.
- B. Equivalent Drug Product Interchange
  - 1. The pharmacist shall not select an equivalent drug product when the prescriber prohibits interchange by any one of the following methods:
    - a. On a prescription generated in written form, the prescriber shall handwrite a mark in a check box labeled "Dispense as Written", or the abbreviation "DAW", or both, and shall manually sign the prescription form.
      - i. For prescriptions reimbursable by the state Medicaid program, the prescriber shall handwrite the words "Brand Necessary" or "Brand Medically Necessary" on the prescription form or on a sheet of paper attached to the prescription form.
    - b. On a prescription generated in oral or verbal form, the prescriber (or the prescriber's agent) shall indicate a specific brand name drug or product is ordered by the practitioner, and the pharmacist shall note such information on the file copy of the prescription.
    - c. On a prescription generated in electronic form, the prescriber shall indicate "Dispense as Written", "DAW", or "Brand Medically Necessary."
  - 2. Where the prescriber has indicated that an equivalent drug product interchange is prohibited, then a non-licensed, non-certified, or non-registered agent of the pharmacy shall not inquire as to a patient's desire for an equivalent drug product interchange.
  - 3. In the event the prescriber has not prohibited equivalent drug product interchange in the manner described above, the pharmacist may select an equivalent drug product for dispensing, provided the patient has been informed of, and has consented to, the proposed cost saving interchange.
  - 4. When the pharmacist selects a biological product rated as interchangeable for the product ordered by the prescriber, the dispensing pharmacist (or his designee) shall communicate to the prescriber by any means,

but no later than five business days following the dispensing date, the specific product dispensed to the patient, including the name of the product and the manufacturer. However, no such communication to the prescriber is required when:

- a. the prescriber prohibited interchange in the manner described above;
- b. there is no product rated as interchangeable or therapeutically equivalent; or
- c. the product dispensed is a refill not changed from the product dispensed on the prior filling of the prescription.
- C. Unless otherwise allowed by law, drugs dispensed on prescription to a patient shall not be accepted for return, exchange, or re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises where they were dispensed.
- D. When a patient or his designee wishes to return previously dispensed prescription drugs to a pharmacy for disposal, the pharmacy shall inform the patient or his designee of the disposal mechanisms available to him. In the event the pharmacy elects to accept such previously dispensed products for disposal, the pharmacy shall comply with the following requirements:
  - 1. From the time of receipt of such products until the time of disposal, the pharmacy shall quarantine such products to keep them separate from its active dispensing stock and shall take appropriate security measures to prevent the theft or diversion of such products.
  - 2. The pharmacy shall comply with the provisions of <u>21 CFR §1317</u> or its successor for the pharmacy's disposal of controlled substances and other non-hazardous waste pharmaceuticals.
  - 3. The pharmacy shall comply with the provisions of 40 CFR §261 or its successor for the pharmacy's disposal of hazardous waste pharmaceuticals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 43:2162 (November 2017), LR 46:793 (June 2020).

# §2519. Prescription Refills; Medication Synchronization and Refill Consolidation

- A. Prescription Refills
  - 1. Limitations on Number of Refills
    - a. The refilling of a prescription for a drug listed in Schedule II is prohibited.
    - b. A prescription for a drug listed in Schedule III or IV may be refilled up to five times if so indicated at the time issued.
    - c. A prescription for a drug listed in Schedule V may be refilled without limitation if so indicated at the time issued subject to the one-year expiration date of the prescription.
    - d. A prescription for a drug not listed as a controlled substance or for a medical device, medical gas, or durable medical equipment may be refilled without limitation if so indicated at the time issued subject to the one year expiration date of the prescription.
  - 2. Refill Authorization. Prescription refills may be dispensed only with the prescriber's authorization, as indicated on the original prescription order. In the absence of the authorized practitioner's instructions on the original prescription, the prescription shall be considered non-refillable. When all refills authorized on the original prescription have been dispensed, then authorization from the prescribing practitioner shall be obtained prior to dispensing; when such authorization has been received, a new prescription shall be prepared and it shall be issued a different prescription number.
  - 3. Patient Request for Continuation of Therapy. When previously authorized refills have been dispensed, or when the previous prescription has expired, and the patient, or his agent or caregiver, requests continuation of therapy, the pharmacy may submit a request to the prescriber for a new prescription. A pharmacy may offer their patient an auto-refill service to facilitate such requests for the life of that prescription. In the absence of a specific request for continuation of therapy from the patient, or his agent or caregiver, the pharmacy shall not submit a request for continuation of therapy to a prescriber.
  - 4. Dispensing of Refills. Prescription refills authorized by the prescriber shall not be dispensed in the absence of a patient, or his agent or caregiver's, request or approval. A pharmacy may offer their patient an auto-refill service to facilitate such requests. This prohibition shall not apply to refills authorized by the prescriber which are to be dispensed to a patient residing in a long-term care facility.
- B. Medication Synchronization and Refill Consolidation. These terms refer to a service which a pharmacist may perform for his patient, at the request of the patient, wherein he may proactively adjust the medication dispensing quantity and/or the refill schedule of a prescription in order to manage the patient's medication therapy, with the goal of improved medication adherence by the patient.

- 1. For the performance of this service, the pharmacist may adjust the dispensing quantity and/or the refill schedule originally ordered by the prescriber; however, the pharmacist shall not exceed the total quantity prescribed [dispensing quantity multiplied by the total number of fills authorized (original plus refills)], or what is otherwise allowed by law.
- 2. With respect to prescriptions for controlled substances where refills have been authorized, pharmacists may utilize partial fills, as described in §2747.C.5 of this Part, but may not exceed the dispensing quantity noted on the original prescription.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004, LR 33:1133 (June 2007), amended by the Department of Health, Board of Pharmacy, LR 42:1519 (September 2016), LR 46:575 (April 2020), LR 47:1644 (November 2021), LR 49:1724 (October 2023).

## §2521. Emergency Refills

A. Using sound professional judgment, a pharmacist may refill adequate medication for a quantity not to exceed a 30-day supply when an emergency for medication has been adequately demonstrated and the prescribing practitioner is not available. The 30-day supply limitation shall not apply to multiple-dose unit-of-use containers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:585 (April 2020), LR 47:1644 (November 2021).

# §2523. Transfer of Prescription Information

- A. Prescription Transfer Requirements
  - 1. Prescriptions for Controlled Dangerous Substances
    - a. The transfer of original prescription information for a controlled substance listed in Schedules III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization, whether or not the pharmacy from which the prescription is transferred is open for business. Transfers are subject to the following requirements:
      - i. The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:
        - (a) invalidation of the prescription;
        - (b) record on the reverse of the invalidated prescription the name, address, and DEA registration of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information;
        - (c) record the date of the transfer and the name of the pharmacist transferring the information.
    - b. The pharmacist receiving the transferred prescription shall record the following:
      - i. Indication of the transferred nature of the prescription.
      - ii. Provide all information required for a prescription for a controlled substance (full name and address of patient; drug name, strength, and dosage form; quantity prescribed and directions for use; and the name, address, and DEA registration of the prescriber) and include:
        - (a) date of issuance of original prescription;
        - (b) original number of refills authorized on original prescription;
        - (c) date of original dispensing;
        - (d) number of valid refills remaining and date(s) and location(s) of previous refill(s);
        - (e) pharmacy's name, address, DEA registration number and prescription number from which the prescription information was transferred;
        - (f) name of pharmacist who transferred the prescription; and
        - (g) pharmacy's name, address, DEA registration number and prescription number from which the prescription was originally filled.
      - iii. The original and transferred prescription(s) shall be maintained for a period of two years from the date of the last refill.

- c. Pharmacies electronically accessing the same prescription record shall satisfy all information requirements of a manual mode for prescription transferal.
- 2. Prescriptions for Drugs Other Than Controlled Dangerous Substances
  - a. The transfer of original prescription information for the purpose of refill dispensing is permissible between pharmacies, subject to the following requirements:
    - i. Prescriptions may be transferred up to the maximum number of refills permitted by the prescriber on the original prescription.
    - ii. The transferring pharmacist, intern, or certified technician shall record the information itemized in Clause 1.a.i above, with the exception of the DEA registration numbers.
    - iii. The receiving pharmacist, intern, or certified technician shall record the information itemized in Subparagraph 1.b above, with the exception of the DEA registration numbers.
  - b. The original and transferred prescription(s) shall be maintained for a period of two years from the date of the last refill.
  - c. Pharmacies electronically accessing the same prescription record shall satisfy all information requirements of a manual mode for prescription transferal.
- B. Pharmacies Using Common Electronic Files
  - 1. Pharmacies using a common electronic file are not required to physically or electronically transfer prescriptions for information dispensing purposes between or among pharmacies participating in the same common prescription file; provided, however any such common file must contain complete and adequate records of such prescriptions, and further, that a hard copy of each prescription transferred or accessed for purposes of refilling shall be generated and maintained at the pharmacy refilling the prescription or to which the prescription is transferred.
  - 2. This accommodation shall comply with all state and federal laws and regulations regarding controlled dangerous substance prescription transfers.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004, amended LR 33:1133 (June 2007), LR 36:756 (April 2010), amended by the Department of Health, Board of Pharmacy, LR 49:67 (January 2023).

## §2525. Prescription Expiration

- A. A prescription for a drug other than a controlled dangerous substance listed in Schedules II through IV shall expire one year after the date written.
- B. A prescription for a controlled dangerous substance shall expire:
  - 1. 90 days after the date of issue if the drug is listed in Schedule II; or
  - 2. six months after the date of issue if the drug is listed in Schedule III or IV.
- C. Expired prescriptions shall not be refillable or renewable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 42:1090 (July 2016), LR 47:1645 (November 2021).

# §2527. Prescription Labeling

- A. An appropriate label shall be affixed to a proper container, and shall bear the following minimum information:
  - 1. pharmacy's name, address, and telephone number;
  - 2. prescription number;
  - 3. authorized prescriber's name;
  - 4. patient's name;
  - 5. date dispensed;
  - 6. drug name and strength;
  - 7. directions for use as indicated;
  - 8. pharmacist's name or initials; and
  - 9. cautionary auxiliary labels, if applicable.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2104 (October 2003), effective January 1, 2004.

## §2529. Pharmacy Prepackaging

- A. *Prepackaging* is the preparation of medication in a unit-of-use container by a pharmacist in a pharmacy prior to the receipt of a prescription for ultimate prescription dispensing by a pharmacist in Louisiana.
- B. Labeling. The label on the prepackaged container shall contain the following minimum information:
  - 1. drug name;
  - 2. dosage form;
  - 3. strength;
  - 4. quantity;
  - 5. name of manufacturer and/or distributor;
  - 6. manufacturer's lot or batch number;
  - 7. date of preparation;
  - 8. pharmacist's initials; and
  - 9. expiration date according to United States Pharmacopeia (USP) guidelines.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004.

## Subchapter C. Compounding of Drugs

# §2531. Purpose and Scope

- A. Purpose. The rules of this Subchapter describe the requirements of minimum current good compounding practices for the preparation of drug formulations by Louisiana-licensed pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates for dispensing and/or administration to patients.
- B. Scope. These requirements are intended to apply to all compounded preparations, sterile and non-sterile, regardless of the location of the patient, e.g., home, hospital, nursing home, hospice, or practitioner's office.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004, LR 41:97 (January 2015).

## §2533. Definitions

A. As used in this Subchapter, the following terms shall have the meaning ascribed to them in this Section: *Biological Safety Cabinet* – a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49, or its successor

Class 100 Environment – an atmospheric environment that contains fewer than 100 particles, of the size 0.5 microns or less in diameter, per cubic foot of air, according to Federal Standard 209E, or its successor.

Component – any ingredient used in the compounding of a drug product.

Compounding – 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 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.

Cytotoxic – any pharmaceutical that has the capability of killing living cells.

*Practitioner Administered Compounds* – products compounded by a licensed pharmacist upon the medical order of a licensed prescriber for administration by a prescriber for diagnostic or therapeutic purposes.

*Preparation* – a compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug. This term will be used to describe compounded formulations.

Sterile Compounding – compounding performed using established aseptic technique and utilizing a laminar air flow hood or other device capable of providing a sterile compounding environment. Sterile compounding shall be used when compounding parenteral medications or products, ophthalmic preparations, or any other preparation requiring sterile techniques.

Sterile Product – any dosage form devoid of viable microorganisms including, but not limited to, parenterals, injectables, and ophthalmics.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2105 (October 2003), effective January 1, 2004, LR 41:97 (January 2015).

## §2535. General Standards

- A. Compounding Practices. Compounded medications may be prepared using prescription medications, over-the-counter medications, chemicals, compounds, or other components.
  - 1. A pharmacy shall have written procedures as necessary for the compounding of drug preparations to assure that the finished preparations have the identity, strength, quality, and purity they are represented to possess.
  - 2. All compounding shall be accomplished utilizing accepted pharmacy techniques, practices, and equipment, and in compliance with the <u>Federal Food, Drug and Cosmetic Act of 1938 (FDCA)</u> as subsequently amended, the current edition of <u>Title 21 of the Code of Federal Regulations (CFR)</u>, and all relevant chapters of the United States Pharmacopeia-National Formulary.
    - a. The compounding of sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of Section 503-A of the FDCA and USP Chapter 797.
    - b. The compounding of non-sterile preparations pursuant to the receipt of a patient-specific prescription shall comply with the provisions of Section 503-A of the FDCA and USP Chapter 795.
    - The compounding of preparations for veterinary use shall comply with the provisions of <u>Section 530</u> of Title 21 of the CFR.
    - d. The compounding of positron emission tomography (PET) drugs shall comply with the provisions of Section 212 of Title 21 of the CFR.
  - 3. Products or duplicates of products removed from the market for the purposes of safety shall not be used to compound prescriptions for human use.
- B. Board Notification. An applicant or pharmacy permit holder who wishes to engage in the compounding of sterile preparations shall notify the board and shall receive approval from the board prior to beginning that practice.
- C. Training and Education. All individuals compounding sterile preparations shall:
  - 1. obtain practical and/or academic training in the compounding and dispensing of sterile preparations;
  - 2. complete a minimum of one hour of Accreditation Council for Pharmacy Education (ACPE) accredited or board-approved continuing education, on an annual basis, related to sterile drug preparation, dispensing, and utilization;
  - 3. use proper aseptic technique in compounding of all sterile preparations, as defined by the pharmacy practice site's policy and procedure manual;
  - 4. qualify through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such persons will be assigned to use to make and dispense sterile preparations; and
  - 5. maintain in the pharmacy practice site a written record of initial and subsequent training and competency evaluations. The record shall contain the following minimum information:
    - a. name of the individual receiving the training/evaluation;
    - b. date of the training/evaluation;
    - c. general description of the topics covered;
    - d. signature of the individual receiving the training/evaluation; and
    - e. name and signature of the individual providing the training/evaluation.
- D. Anticipated Use Preparations. The pharmacist shall label any excess compounded preparation so as to reference it to the formula used and the assigned lot number and estimated beyond use date based on the pharmacist's professional judgment and/or other appropriate testing or published data.
- E. Veterinarian-Administered Compounds, also referred to as Pharmacy-Generated Drugs
  - 1. Upon receipt of a valid non-patient-specific medical order from a licensed veterinarian, the pharmacy may compound a preparation intended for administration to an animal patient by the veterinarian.
  - 2. These preparations may not be distributed to any third party by the pharmacy, nor may these preparations be further re-sold or distributed by the veterinarian ordering the preparation from the pharmacy.
  - 3. This authorization is primarily intended to facilitate the preparation of medication needed for emergency use in a veterinary office practice. Given the limited application of this authorization, which allows these products to be prepared using less rigorous standards applicable to compounding as opposed to the more rigorous standards appliable to manufacturing processes, the compounding pharmacy preparing these products shall be limited in the amount of such products they can prepare.
    - a. No Louisiana-licensed pharmacy may distribute any amount of practitioner-administered compounds in excess of 5 percent of the total amount of drug products dispensed and/or distributed from their pharmacy.

- b. The 5 percent limitation shall be calculated on a monthly basis and shall reference the number of dosage units.
- c. For those Louisiana-licensed pharmacies located outside Louisiana, the total amount distributed and/or dispensed shall reference the pharmacy's total business within the state of Louisiana.
- 4. The provisions of this Subsection E notwithstanding, pharmacists intending to engage in the compounding of veterinary preparations pursuant to non-patient-specific medical orders from veterinarians should be aware that federal law or rule may not permit such activity by a licensed pharmacy, and further, such pharmacists should be aware that the board's rules cannot legitimize an activity that is not permitted under federal law or rule, and further, such pharmacists should be aware that while this activity is permitted by the board, pharmacists engaging in this activity remain subject to the full force and effect of federal law enforcement.
- F. Compounding Copies of Commercial Drug Products.
  - 1. Copies of commercial drug products contain the same active pharmaceutical ingredient(s) in the same, similar, or easily substitutable dosage strength which can be used by the same route of administration. Changes in strength of less than 10 percent from the commercial drug product shall not be considered significant enough to warrant the preparation of a copy of a commercial drug product. In the event a prescriber determines a change in the formulation of a commercial drug product is necessary to produce a significant clinical difference for the patient and that determination is documented on the prescription, the pharmacy may prepare a variation of the commercial drug product, provided:
    - a. the prescriber's determination shall identify both the relevant change requested and the clinically significant difference the change will produce for the patient; and
    - b. the pharmacy does not prepare copies of commercial drug products regularly or in inordinate amounts.
  - 2. A pharmacy may prepare a copy of a commercial drug product when that product has been discontinued and is no longer marketed, or the product appears on the drug shortage list maintained by the federal Food and Drug Administration, or the product is temporarily unavailable as demonstrated by invoice or other communication from the distributor or manufacturer.
- G. Labeling of Compounded Preparations.
  - 1. For patient-specific compounded preparations, the labeling requirements of <u>R.S. 37:1225</u>, or its successor, as well as §2527 of this Chapter, or its successor shall apply.
  - 2. For veterinarian administered compounds, the label shall contain, at a minimum, the following data elements:
    - a. pharmacy's name, address, and telephone number;
    - b. veterinarian's name;
    - c. name of preparation;
    - d. strength and concentration;
    - e. lot number;
    - f. beyond use date;
    - g. special storage requirements, if applicable;
    - h. identification number assigned by the pharmacy; and
    - i. name or initials of pharmacist responsible for final check of the preparation.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 23:1316 (October 1997), LR 29:2105 (October 2003), effective January 1, 2004, LR 41:97 (January 2015), amended by the Department of Health, Board of Pharmacy, LR 42:891 (June 2016), LR 46:577 (April 2020), LR 49:66 (January 2023).

## Subchapter D. Prescription Drugs

## §2541. Standing Orders for Distribution of Naloxone and Other Opioid Antagonists

- A. Given the current public health emergency relative to the misuse and abuse of opioid derivatives, public health officials have strongly recommended the widespread availability of naloxone and other opioid antagonists to addicts and their caregivers as well as first responders in the community.
- B. For as long as naloxone and other opioid antagonists remain classified as prescription drugs by the federal Food and Drug Administration, pharmacists must secure a prescription or order from a prescriber with the legal authority to prescribe the drug product in order to dispense or distribute the drug product.

- C. The Louisiana Legislature has adopted a number of laws designed to facilitate the distribution and dispensing of naloxone and other opioid antagonists beyond the person who would need the medication on an emergent basis to manage an opioid-related drug overdose, more specifically to first responders as well as caregivers and family and friends of potential patients.
  - Act 253 of the 2014 Legislature authorized prescribers to issue prescriptions for naloxone and other
    opioid antagonists to first responders, and further, authorized pharmacists to recognize such prescriptions
    as legitimate orders for the dispensing and distribution of naloxone and other opioid antagonist drug
    products, and further, authorized first responders to have and hold those drug products ready for
    administration in emergent conditions to manage opioid-related drug overdoses.
  - 2. Act 192 of the 2015 Legislature authorized medical practitioners to prescribe naloxone or another opioid antagonist without having previously examined the individual to whom the medication would be administered, but only under certain conditions specified in the legislation, including the requirement for the prescriber to provide the recipient of the drug with all training and education required for the safe and proper administration of the drug product.
  - 3. Act 370 of the 2016 Legislature authorized medical practitioners to issue nonpatient-specific standing orders to pharmacists authorizing the distribution of naloxone and other opioid antagonists to anyone who might be in a position to assist a patient in the emergent management of an opioid-related drug overdose, but only in compliance with these rules.
    - a. A nonpatient-specific standing order for the facilitated distribution of naloxone or other opioid antagonist issued by a medical practitioner licensed by the State of Louisiana shall expire one year after the date of issuance.
    - b. A Louisiana-licensed pharmacist may distribute naloxone or other opioid antagonist according to the terms of the nonpatient-specific standing order issued by a Louisiana-licensed medical practitioner until the expiration date of the standing order. No pharmacist shall distribute naloxone or other opioid antagonist pursuant to a standing order more than one year after the date of issuance of the standing order.
    - c. Before releasing the naloxone or other opioid antagonist drug product to the recipient, the pharmacist shall verify the recipient's knowledge and understanding of the proper use of the drug product, including, at a minimum:
      - i. techniques on how to recognize signs of an opioid-related drug overdose;
      - ii. standards and procedures for the storage and administration of the drug product; and
      - iii. emergency follow-up procedure including the requirement to summon emergency services either immediately before or immediately after administering the drug product to the individual experiencing the overdose.
    - d. To comply with the recordkeeping requirements found elsewhere in the board's rules, the pharmacist shall attach a copy of the standing order to the invoice or other record of sale or distribution, and further, shall store these transaction documents with the other distribution records in the pharmacy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182. HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 43:958 (May 2017).

[End of Chapter 25]

## **Chapter 27. Controlled Dangerous Substances**

## Subchapter A. General Provisions

## §2701. Definitions

A. Words not defined in this Chapter shall have their common usage and meaning as stated in the *Merriam-Webster's Collegiate Dictionary – Tenth Edition*, as revised, and other similarly accepted reference texts. As used in this Chapter, the following terms shall have the meaning ascribed to them in this Section unless the context clearly indicates otherwise:

Administer or Administration – the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or any other means.

Agent – an individual who acts on behalf or at the direction of a manufacturer, distributor, or other licensee, but does not include a common or contract carrier, public warehouseman, or employee thereof.

Ambulatory Surgical Center or Surgical Center – a facility licensed by the department to operate as an ambulatory surgery center.

BNDD – United States Bureau of Narcotics and Dangerous Drugs.

Board – the Louisiana Board of Pharmacy.

Central Fill Pharmacy – a pharmacy which provides centralized dispensing services to other pharmacies, in compliance with the provisions of §1141 of the board's rules.

Certified Animal Euthanasia Technician – an individual authorized by law and certified by the Louisiana State Board of Veterinary Medicine to practice animal euthanasia.

*CFR* – Code of Federal Regulations.

Client Pharmacy – a pharmacy which has engaged the services of a central fill pharmacy.

Controlled Dangerous Substance or Controlled Substance – any substance defined, enumerated, or included in federal or state statute or regulations, 21 CFR §1308.11 - 15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled dangerous substance by amendment or supplementation of such regulations or statute. The term shall not include distilled spirits, wine, malt beverages, or tobacco.

*CRT* – cathode ray tube video display unit.

DEA – United States Drug Enforcement Administration.

*Deliver* or *Delivery* – the actual, constructive, or attempted transfer of a drug or device containing a controlled substance, from one person to another, whether or not for consideration, or whether or not there exists an agency relationship.

*Dentist* – an individual authorized by law and licensed by the Louisiana State Board of Dentistry to engage in the practice of dentistry.

Department – the Louisiana Department of Health.

Dispense or Dispensing – means the interpretation, evaluation, and implementation of a prescription drug order for a controlled substance, 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.

*Dispenser* – an individual currently licensed, registered, or otherwise authorized by the appropriate licensing board to dispense drugs or devices containing controlled substances to his own patients in the course of professional practice.

Distribute or Distributing – means the delivery of a drug or device containing a controlled substance in response to a non-patient specific purchase order, requisition, or similar communication, other than by administering or dispensing.

*Distributor* or *Wholesaler* – a facility authorized by law and licensed by the Louisiana Board of Drug and Device Distributors to engage in the distribution of drugs or devices, including controlled substances.

Drug –

- 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 disease in humans or animals;
- b. any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals; or
- c. any substance other than food intended to affect the structure or any function of the body of humans or animals.

Drug Detection Canine Trainer – an individual qualified to conduct experiments using controlled substances in training canines to detect the presence of contraband controlled dangerous substances.

Drug Detection Canine Handler – an individual qualified to handle canines in the detection of contraband controlled substances.

*Electronic Prescription* – a prescription generated, signed, and transmitted in electronic form.

*Emergency Clinic* – a facility staffed by at least one physician and other licensed medical personnel for the purpose of providing emergency medical treatment.

Facility – an organized health care setting authorized by law and licensed by the department to engage in the provision of health care.

*Hemp Facility* – a facility licensed by the Louisiana Department of Agriculture and Forestry as a hemp seed producer, hemp grower, hemp handler or hemp processor.

*Hospital* – a facility licensed by the department to operate as a hospital.

LDAF – Louisiana Department of Agriculture and Forestry, or its successor.

License – a Louisiana Controlled Dangerous Substances (CDS) License.

Licensee – an individual or facility in possession of a Louisiana CDS License.

*Manufacturer* – a person authorized by law and licensed by the federal Food and Drug Administration to engage in the production of drugs, including controlled substances.

Narcotic Treatment Program – a program authorized by law and licensed by the department and the federal Drug Enforcement Administration to operate a substance abuse program using narcotic replacement procedures for individuals dependent upon opium, heroin, morphine, or any other derivative or synthetic drug in that classification of drugs.

*Optometrist* – an individual authorized by law and licensed by the Louisiana State Board of Optometry Examiners to engage in the practice of optometry.

*Person* – an individual, corporation, partnership, association, or any other legal entity, including government or governmental subdivision or agency.

*Pharmacist* – an individual authorized by law and licensed by the board to engage in the practice of pharmacy. *Pharmacy* – a place authorized by law and permitted by the board to procure, possess, compound, distribute, and dispense drugs, including controlled substances.

*Physician* – an individual authorized by law and licensed by the Louisiana State Board of Medical Examiners to engage in the practice of medicine.

*Podiatrist* – an individual authorized by law and licensed by the Louisiana State Board of Medical Examiners to engage in the practice of podiatry.

*Practice Affiliation* – a practice relationship, collaboration, or practice under the supervision of a physician licensed to practice medicine, applicable to advanced practice registered nurses and physician assistants.

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

Prescribe or Prescribing – to order a drug or device to be administered or dispensed to a specific patient.

Prescriber – an individual currently licensed, registered, or otherwise authorized by the appropriate licensing board to prescribe drugs in the course of professional practice.

*Prescription* or *Prescription Drug Order* – an order from a practitioner authorized by law to prescribe a drug or device that is patient specific and is to be preserved on file as required by law or regulation.

Researcher – an individual qualified to conduct medical, educational, or scientific experiments on animals, humans, or in laboratories which require the use of controlled substances. For the purpose of this Chapter, manufacturers which use controlled substances in the manufacturing process, but do not manufacture controlled substances as an end product, shall be considered researchers and not manufacturers as defined in R.S. 40:961(24)<sup>1</sup>.

Reverse Distribute – to acquire controlled substances from another registrant or law enforcement agency for the purpose of:

- a. return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or
- b. destruction.

Reverse Distributor – is a person registered by the DEA as a reverse distributor.

Sales Representative or Professional Medical Representative – an individual employed by a manufacturer or distributor and authorized by the employer to receive, possess, and deliver controlled substances to a person licensed to possess controlled dangerous substances.

Supplier – any person registered by the DEA who is entitled to fill order forms for controlled substances. Third-Party Logistics Provider – a person who provides or coordinates warehousing, facilitation of delivery, or other logistic services for a legend drug or legend device in interstate or intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not take ownership of the legend drug or legend device nor have responsibility to direct the sale or disposition of the legend drug or legend device. Veterinarian – an individual authorized by law and licensed by the Louisiana State Board of Veterinary Medicine to engage in the practice of veterinary medicine.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2127 (October 2008), amended by the Department of Health, Board of Pharmacy, LR 46:569 (April 2020), LR 46:973 (June 2020), LR 47:1640 (November 2021), LR 48:494 (March 2022).

## §2703. Controlled Substances

#### A. Classification

- Controlled substances are specifically identified by reference, as provided in R.S. 40:961 et seq., or its successor, and 21 CFR §1308 et seq., or its successor. Schedules I, II, III, IV, and V shall, unless and until added to pursuant to R.S. 40:961 et seq., or its successor, consist of the drugs or other substances, by whatever official name, common or usual name, chemical name, or trade name designated, listed in R.S. 40:961 et seq., or its successor.
- B. Schedules. Controlled substances are categorized into various schedules based upon the degrees of potential for abuse, as follows:
  - 1. Schedule I:
    - a. the drug or other substance has a high potential for abuse;
    - the drug or other substance has no currently accepted medical use in treatment in the United States;
       and
    - there is a lack of accepted safety for use of the drug or other substance under medical supervision.
  - 2. Schedule II:
    - a. the drug or other substance has a high potential for abuse;
    - b. the drug or other substance has a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions; and
    - c. abuse of the drug or other substance may lead to severe psychological or physical dependence.
    - d. when used, Schedule II-N (or 2N) shall refer to the non-narcotic drugs listed in Schedule II.
  - 3. Schedule III:
    - a. the drug or other substance has a potential for abuse less than the drugs or other substances listed in Schedules I and II above:
    - b. the drug or other substance has a currently accepted medical use in treatment in the United States; and
    - c. abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence;
    - d. when used, Schedule III-N (or 3N) shall refer to the non-narcotic drugs listed in Schedule III.
  - 4. Schedule IV:
    - a. the drug or other substance has a low potential for abuse relative to the drugs or other substances listed in Schedule III;
    - the drug or other substance has a currently accepted medical use in treatment in the United States;
       and
    - c. abuse of the drug or other substance may lead to limited psychological or physical dependence relative to the drugs or other substances listed in Schedule III.
  - 5. Schedule V
    - a. the drug or other substance has a low potential for abuse relative to the drugs or other substances listed in Schedule IV;
    - the drug or other substance has a currently accepted medical use in treatment in the United States;
       and
    - c. abuse of the drug or other substance may lead to limited psychological or physical dependence relative to the drugs or other substances listed in Schedule IV.
- C. Scheduling of Additional Controlled Substances. <u>R.S. 40:963</u> authorizes the secretary of the department to add additional substances to the schedules identified in Subsection B. In making the determination to add a substance, the secretary is required to make certain findings, as identified in <u>R.S. 40:963</u>.
  - 1. In determining whether a drug has a "stimulant effect" on the central nervous system, the secretary shall consider, among other relevant factors, whether there is substantial evidence that the drug may produce any of the following:
    - a. extended wakefulness;
    - b. elation; exhilaration or euphoria (exaggerated sense of well-being);
    - c. alleviation of fatigue;
    - d. insomnia, irritability, or agitation;
    - e. apprehension or anxiety;
    - f. flight of ideas, loquacity, hypomania or transient delirium.

- 2. In determining whether a drug has a "depressant effect" on the central nervous system, the secretary shall consider, among other relevant factors, whether there is substantial evidence that the drug may produce any of the following:
  - a. calming effect or relief of emotional tension or anxiety;
  - b. drowsiness, sedation, sleep, stupor, coma, or general anesthesia;
  - c. increase of pain threshold;
  - d. mood depression or apathy;
  - e. disorientation, confusion or loss of mental acuity.
- 3. In determining whether a drug is "habit-forming," the secretary shall consider, among other relevant factors, whether there is substantial evidence that the drug may produce any of the following:
  - a. a psychological or physical dependence on the drug (compulsive use);
  - b. euphoria;
  - c. personality changes;
  - d. transient psychoses, delirium, twilight state, or hallucinations;
  - e. chronic brain syndrome;
  - f. increased tolerance or a need or desire to increase the drug dosage;
  - g. physical dependence or a psychic dependence evidenced by a desire to continue taking the drug for a sense of improved well-being that it engenders;
  - h. pharmacological activity similar or identical to that of drugs previously designated as habit-forming.
- 4. In determining whether a drug has a "hallucinogenic effect," the secretary shall consider, among other relevant factors, whether there is substantial evidence that the drug may produce hallucinations, illusions, delusions, or alteration of any of the following:
  - a. orientation with respect to time or place;
  - consciousness, as evidenced by confused states, dreamlike revivals of past traumatic events or childhood memories;
  - c. sensory perception, as evidenced by visual illusions, synesthesia, distortion of space and perspective;
  - d. motor coordination;
  - e. mood and affectivity, as evidenced by anxiety, euphoria, hypomania, ecstasy, autistic withdrawal;
  - f. ideation, as evidenced by flight of ideas, ideas of reference, impairment of concentration and intelligence;
  - g. personality, as evidenced by depersonalization and derealization, impairment of conscience and of acquired social and cultural customs.
- 5. The secretary may determine that a substance has a potential for abuse because of its depressant or stimulant effect on the central nervous system or its hallucinogenic effect if:
  - a. there is evidence that individuals are taking the drug or drugs containing such a substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community;
  - b. there is significant diversion of the drug or drugs containing such a substance from legitimate drug channels:
  - c. individuals are taking the drug or drugs containing such a substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs in the course of his professional practice; or
  - d. the drug or drugs containing such a substance are new drugs so related in their action to a drug or drugs already listed as having a potential for abuse to make it likely that the drug will have the same potentiality for abuse as such drugs, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.
- D. Combination Drugs; Exemption From Certain Requirements. Pursuant to <u>R.S. 40:965</u>, the list of combination drugs and preparations exempted from the application of this Chapter shall be the List of Exempted Prescription Products as identified in the current Code of Federal Regulations, specifically at <u>21 CFR 1308.32</u>.
- E. Excepted Drugs; Exemption From Certain Requirements. Pursuant to <u>R.S. 40:965</u>, the list of excepted drugs and preparations which contain any depressant or stimulant substance listed in Subsections 1, 2, 3, or 4 of Schedule III shall be the List of Exempted Prescription Products as identified in the current Code of Federal Regulations, specifically at <u>21 CFR 1308.32</u>.
- F. Changes in the Schedule of Controlled Substances. Pursuant to changes in the schedule of a controlled substance by either the United States Drug Enforcement Administration or the State of Louisiana, all licensees shall adhere to the more stringent requirement.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2128 (October 2008).

## §2704. Added Controlled Dangerous Substances

[This section reserved for use by the Department of Health, for the purpose of emergency scheduling actions for new substances in Schedule I, or for dangerous drug stop orders.]

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:962 and R.S. 40:963.

## Subchapter B. Licenses

## §2705. Licenses and Exemptions

- A. Every person who conducts research with, manufactures, distributes, procures, possesses, prescribes, or dispenses any controlled dangerous substance within this state, including third-party logistics providers, or who proposes to engage in the research, manufacture, distribution, procurement, possession, prescribing, or dispensing of any controlled dangerous substance within this state shall obtain a controlled dangerous substance (CDS) License from the board prior to engaging in such activities. Only persons actually engaged in such activities are required to obtain a CDS license; related or affiliated persons, e.g., stockholder in manufacturing corporation, who are not engaged in such activities, are not required to be licensed. The performance of such activities in the absence of a valid CDS license shall be a violation of R.S. 40:973 and this Part
- B. The following persons are exempt from the CDS license requirements of this Chapter:
  - 1. a manufacturer's or distributor's workman, contract carrier, warehouseman or any employee thereof whose handling of controlled substances is in the usual course of his business or employment while on the premises of the employer or under direct transfer orders of the employer.
  - 2. a person who obtains or possesses a controlled substance pursuant to a valid prescription, either for his own use or for the use of a member of his household or for the administration to an animal owned by him or a member of his household;
  - 3. an agent or employee of any licensed manufacturer, distributor, dispenser or researcher in the course of his employment and only on the premises of his employer, but not a sales representative or professional medical representative.

#### C. Practitioners

- 1. The issuance of a CDS license to a practitioner, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential issued by a standing professional board in the state of Louisiana or other agency of competent jurisdiction.
- For the purpose of prescribing controlled substances, a Louisiana CDS license issued to a practitioner shall be valid in any location in Louisiana; however, the procurement and possession of controlled substances shall require a separate CDS license for each such location where controlled substances are possessed.
- 3. A prescribing practitioner desiring to procure and possess controlled substances at only one location need only obtain a single CDS license.
- 4. A physician in possession of the appropriate credential issued by the Louisiana State Board of Medical Examiners may apply for and be issued a CDS license to authorize the prescription or recommendation of the following controlled substances classified in Schedule I: marijuana, tetrahydrocannabinols, and synthetic derivatives of tetrahydrocannabinols; provided however that such prescriptions or recommendations shall only be authorized for therapeutic use in compliance with R.S. 40:1046.

#### D. Pharmacies

- 1. The issuance of a CDS license to a pharmacy, and the renewal thereof, shall require the possession of a valid and verifiable permit to operate a pharmacy issued by the board.
- 2. A Louisiana CDS license issued to a pharmacy shall be valid for the premises identified on the license.
- 3. The possession of controlled substances under the control of the pharmacy at a different location shall require a separate CDS license for each separate location.
- E. Healthcare Facilities and Hemp Facilities
  - 1. The issuance of a CDS license to a healthcare facility, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential issued by the department, or its successor.
  - 2. The issuance of a CDS license to a hemp facility, and the renewal thereof, shall require a valid and verifiable license as a hemp seed producer, hemp grower, hemp handler or hemp processor issued by the

Louisiana Department of Agriculture and Forestry (LDAF).

- F. Manufacturers, Distributors and Third-Party Logistics Providers
  - 1. The issuance of a CDS license to a manufacturer, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential from the Food and Drug Control Unit of the Office of Public Health in the Louisiana Department of Health, or its successor. Further, the applicant shall submit to an initial and periodic inspection by the board or its designee.
  - 2. The issuance of a CDS license to a distributor, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential from the Food and Drug Control Unit of the Office of Public Health in the Louisiana Department of Health, as well as the Louisiana Board of Drug and Device Distributors, or their successors. Further, the applicant shall submit to an initial and periodic inspection by the board or its designee.
  - 3. The issuance of a CDS license to a third-party logistics provider, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential from the Louisiana Board of Drug and Device Distributors.
  - 4. The sale or transportation of controlled substances within the State of Louisiana by manufacturers, distributors and third-party logistics providers located outside the State of Louisiana shall require the possession of a valid CDS license issued by the board prior to the engagement of such activities.

#### G. Researchers

- The issuance of a CDS license to a researcher, and the renewal thereof, shall require the attachment to the
  application of a properly completed form supplied by the board describing the research, and further, when
  the research involves human subjects, the attachment to the application of proof of approval by the
  appropriate Institutional Review Board.
- 2. A determination of qualification shall be made by the board or its designee.
- H. Drug Detection Canine Trainers/Handlers
  - 1. The issuance of a CDS license to a drug detection canine trainer or handler, and the renewal thereof, shall require the attachment to the application of a properly completed form supplied by the board describing the policies and procedures for the use of controlled substances.
  - 2. A determination of qualification shall be made by the board or its designee.
  - 3. This Section shall not apply to a law enforcement agency or its personnel in the performance of its official duties.
- I. Certified Animal Euthanasia Technician. The issuance of a CDS license to a certified animal euthanasia technician, and the renewal thereof, shall require the possession of a valid and verifiable license or other credential issued by the Louisiana Board of Veterinary Medicine, or its successor.
- J. Professional Medical Representatives. The issuance of a CDS license to a professional medical representative, and the renewal thereof, shall require the attachment to the application of written verification of employment from the manufacturer or distributor, as well as their authorization for the representative to receive, possess, and deliver controlled substances.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2129 (October 2008), amended LR 39:312 (February 2013), amended by the Department of Health, Board of Pharmacy, LR 46:570 (April 2020), LR 47:1640 (November 2021), LR 48:494 (March 2022).

## §2707. Licensing Procedures

- A. Application for Initial Issuance of CDS License
  - 1. An individual or other entity desiring to obtain a Louisiana CDS license shall complete the application form supplied by the board and submit it with the required attachments and appropriate fees, as set forth in R.S. 40:972 and R.S. 40:1013, to the board.
  - 2. The applicant shall provide a complete street address reflecting the location where the applicant will engage in the activity for which a Louisiana CDS license is required. The board shall issue only one CDS license for each applicant at each such location.
  - 3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
  - 4. Applicants not in possession of a valid and verifiable license or other credential from a standing professional board of the State of Louisiana, or from the Department of Health, Bureau of Health Services Financing, Health Standards, or their successors, or from the Louisiana Department of Agriculture and Forestry, shall submit to a criminal history record check upon request by the board. The applicant shall pay for the cost of the criminal history record check. The board shall evaluate the findings

- of the report of the criminal history record check prior to the issuance of the CDS license.
- 5. An individual or other entity who knowingly or intentionally submits a false or fraudulent application shall be deemed to have committed a prohibited act under R.S. 40:961 et seq. or its successor.
- 6. A CDS license shall be valid for a period of one year, and shall expire annually on the date of initial licensure unless revoked sooner in accordance with the provisions of the <u>Uniform Controlled Dangerous Substances Law</u> or these rules.
- 7. Practitioners in possession of a temporary or restricted license issued by a standing professional board of competent jurisdiction in the state of Louisiana may be issued a temporary or restricted Louisiana CDS license adhering to the limitations or restrictions of their board license.

#### B. Application for Renewal of CDS License

- 1. A licensee shall complete the application for renewal of a CDS license and submit same to the board prior to the expiration date of the current license. The application shall be submitted in such form and contain such data and attachments as the board may require and be accompanied by the appropriate fees, as set forth in R.S. 40:972 and R.S. 40:1013.
- 2. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fees.
- 3. A CDS license not renewed by the expiration date shall be classified as expired. A licensee shall not engage in any activity requiring a valid CDS license while his license is expired.
- 4. A CDS license not renewed within 30 days following the expiration date shall be automatically terminated by the board. The reissuance of a terminated CDS license shall require compliance with the board's reinstatement procedures.

## C. Application for Reinstatement of Terminated, Suspended, or Revoked CDS License

- 1. The applicant shall complete an application form for this specific purpose supplied by the board; the application shall require the inclusion of the annual renewal fee and delinquent fee identified in R.S. 40:972 and the program fee identified in R.S. 40:1013.
- 2. An application for the reinstatement of a terminated credential which has been expired:
  - a. less than one year may be approved by the board's administrative personnel;
  - b. more than one year but less than five years may be approved by a member of the board charged with such duties;
  - c. more than five years may only be approved by the full board following a hearing to determine whether the reinstatement of the credential is in the public's best interest.
- 3. An application for the reinstatement of a CDS license suspended or revoked as a consequence of the suspension or revocation of the primary credential by the issuing agency shall require verification of the reinstatement of the primary credential. Where the issuing agency reinstating the primary credential has restricted any privileges for controlled substances, those restrictions shall be attached to the reinstated CDS license. Where the agency reinstating the primary credential has placed that credential on probation for any period of time, the CDS license shall be placed on probation for the same period of time.
- 4. An application for the reinstatement of a CDS license for a pharmacy which was suspended or revoked by the board may only be approved by the full board following a hearing to determine whether the reinstatement of the license is in the public's best interest. For all other CDS licenses, the reinstatement may be approved by the joint consent of the chair of the reinstatement committee and the board president without the necessity of a hearing; when such approvals are issued, staff shall prepare a reinstatement order for the president's signature.
- 5. Applications requiring a reinstatement hearing shall be accompanied by payment of the administrative hearing fee as identified at R.S. 37:1184<sup>2</sup>.

## D. Maintenance of CDS Licenses

- 1. A CDS license is valid only for the entity or person to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a license be valid for any premises other than the business location for which it is issued.
- 2. In order to maintain a CDS license, the applicant shall maintain a federal license required by federal law to engage in the manufacture, distribution, prescribing, or dispensing of controlled substances.
- 3. The licensee shall inform the board of any and all changes to its business location/address within 10 days, with documentation, attesting to any change of business location/address, with notice to include both the old and new address. A change in business address of a facility may require an inspection by the board or its designee.
- 4. A duplicate or replacement license shall be issued upon the written request of the licensee and a payment of the fee shall be charged as provided by <u>R.S. 40:972</u>. A duplicate or replacement license shall not serve or be used as an additional or second license.

- 5. A facility changing ownership shall notify the board in writing 15 calendar days prior to the transfer of ownership.
  - a. A change of ownership is evident under the following conditions:
    - i. sale
    - ii. death of a sole proprietor;
    - iii. the addition or deletion of one or more partners in a partnership;
    - iv. bankruptcy sale; or
    - v. a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original CDS license.
  - b. The new owner(s) shall submit a properly completed application, with all required attachments and appropriate fee, to the board.
  - c. Upon the receipt of the new CDS license, the previous licensee shall:
    - i. notify the board of the transaction, including the identity of the new owner(s); and
    - ii. surrender his CDS license to the board.
  - d. A CDS license is not transferable from the original owner to a new owner.
  - e. A change in ownership may require an inspection by the board or its designee.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2131 (October 2008), amended by the Department of Health, Board of Pharmacy, LR 43:957 (May 2017), LR 46:570 (April 2020), LR 47:1641 (November 2021).

## §2709. Actions on Applications

- A. Upon receipt of a properly completed application and appropriate fees from a qualified applicant, the board shall issue a Louisiana CDS license to the applicant, unless the board intends to deny the application.
- B. The board may deny an application for the issuance or renewal of a CDS License for cause. For purposes of this Section, the term "for cause" includes surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2132 (October 2008).

# §2711. Actions on Licenses

- A. The board may refuse to renew a CDS license, or may suspend or revoke an existing CDS license, if the licensee has violated, or been found guilty of violating, any federal or state laws or regulations relating to controlled substances.
- B. Violations Committee
  - Informal Hearings. The violations committee of the board may conduct an informal non-adversarial hearing with a licensee properly noticed of the inquiry regarding the issues to be discussed. The committee shall receive information and deliberate as to a cause of action regarding a potential violation. By an affirmative majority vote of the committee members, they may recommend a course of action to the full board, or they may dismiss the allegations. Should the committee recommend a course of action to the full board, the committee members participating in that decision shall not be permitted to participate in subsequent formal administrative hearings pertaining to the complaint or alleged violation(s) heard by the committee, unless the licensee allows otherwise.
  - 2. Interlocutory Hearings. By interlocutory, or summary, hearing, the committee may summarily suspend a CDS license prior to a formal administrative board hearing wherein, based upon the committee's judgment and reflected by adequate evidence and an affirmative majority decision, the licensee poses a danger to the public's health, safety, and welfare, and the danger requires emergency action.
    - a. Summons Notice. A summary proceeding summons notice shall be served at least five days before the scheduled hearing to afford the licensee an opportunity to be heard with respect to a potential summary suspension action. The notice shall contain a time, place, nature, and the grounds asserted relative to the alleged conduct warranting summary suspension.
    - b. Burden of Proof. Legal counsel shall have the burden of proof to support the contention the public's health, safety, or welfare is in danger and requires summary or emergency action.

- c. Evidence. The licensee shall have the right to appear personally, to be represented by counsel, or both, to submit affidavits, documentary evidence, or testimony in response to the cause of action asserted as the basis for the summary suspension.
- d. Decision. The committee shall determine whether to grant or deny the request for summary suspension based upon adequate evidence with an affirmative majority vote substantiated by finding(s) of fact and conclusion(s) of law the public's health, safety, or welfare is in danger and requires emergency or summary action.
- e. Report. The committee shall submit their findings and interlocutory decree to the board when rendered.
- f. Suspensive Duration. The summary suspension decree shall be followed by a formal administrative hearing within 30 days from receipt of notice by the licensee.
- C. Consent Agreements. A licensee may enter into a consent agreement with the board on any matter pending before the board. A consent agreement is not final until the board approves the consent agreement by an affirmative majority vote of the board. If the consent agreement is rejected in full or part, the matter shall be heard at the next regularly scheduled formal administrative hearing. However, nothing herein shall be construed to limit the board from modifying a consent agreement, with the licensee's approval, to include less severe sanctions than those originally agreed to in a pending consent agreement.
- D. Formal Administrative Hearing.
  - 1. Authority. The board shall convene a formal administrative hearing pertaining to the ability to hold a CDS license, in accordance with the Administrative Procedure Act, <u>R.S. 49:950</u> et seq., with authority to take disciplinary action pursuant to <u>R.S. 40:975</u>.
  - 2. *Ex-Parte* Communication. Once a formal administrative hearing has been initiated and notice served, board members participating in the decision process shall not communicate with a licensee or a licensee's attorney concerning any issue of fact or law involved in the formal administrative hearing.
  - 3. Notice. A formal administrative hearing may be initiated upon proper notice to a licensee and held at a designated time and place based upon the following grounds:
    - a. violation sufficient evidence or a serious complaint of an alleged violation to require a formal hearing shall be directed to legal or special counsel for administrative prosecution to justify a formal hearing;
    - b. failure to respond a failure by the licensee to respond to a violations committee informal hearing;
    - c. irresolvable issues a violations committee informal hearing failed to resolve all issues and requires further formal action;
    - d. irreconcilable issues an interlocutory hearing failed to resolve all pertinent pending issues thus requiring further formal action; or
    - e. reaffirmation reaffirmation of an interlocutory decree.
    - f. requirement a formal administrative hearing is required.
- E. Formal Administrative Hearing Procedures.
  - 1. Hearing Officer. The presiding hearing officer may be the board president, a vice-president, or other individual appointed by the president or his successor. The hearing officer shall have the responsibility to conduct a fair and impartial proceeding with the administrative duty as well as the authority to:
    - a. convene a formal administrative hearing;
    - b. rule on motions and procedural questions arising during the hearing such as objections or admissibility of evidence or examination of witnesses;
    - c. issue or direct staff to issue subpoenas;
    - d. declare recess;
    - e. maintain order;
    - f. enforce a standard of conduct to insure a fair and orderly hearing; and
    - g. remove any disruptive person from the hearing.
  - 2. Oaths. The presiding hearing officer, executive director, or other board designee may administer oaths.
  - 3. Jury. The board, comprised of a quorum of members, shall serve as an administrative jury to hear and determine the disposition of the pending matter based on the finding(s) of fact and conclusion(s) of law by receiving evidence and reaching a decision and ordering sanctions by an affirmative majority record vote of board members participating in the decision process.
  - 4. Hearing Clerk. The board's executive director shall serve as the hearing clerk and shall maintain hearing records.
  - 5. Prosecutor. The legal or special counsel shall prosecute the pending matter.
  - 6. Recorder. The board-designated stenographer shall record all testimony dictated and evidence received at the hearing. The utilization of recording equipment may be employed.

#### 7. Agenda

- a. Docket. Contested matters shall be identified by reference docket number and caption title.
- b. Complaint. The complaint may be read, unless waived by the licensee.

#### 8. Order

a. Opening Statements. An opening statement by legal or special counsel may present a brief position comment with an outline of evidence to be offered. The licensee or licensee's legal counsel may present an opening defense position statement.

#### b. Evidence

- Testimony Received. Testimony shall be received under oath administered by the presiding hearing officer, the executive director, or other staff or board member designated by the hearing officer.
- ii. Evidence Introduction. All parties shall be afforded an opportunity to present evidence on all issues of fact and argue on all issues of law and respond by direct testimony, followed with cross examination as may be required for a full and true disclosure of the facts. The direct presentation of evidence shall be introduced by the legal or special counsel and shall be followed by the licensee, either in proper person or by legal counsel, by direct cross-examination or rebuttal, or any combination thereof.
- iii. Examination. Witnesses may be directly examined and cross-examined. Additionally, witnesses and licensees may be questioned by members of the jury on matters for clarification.
- iv. Rule Interpretation. Liberal rules of evidence shall be employed by the presiding hearing officer to provide adequate facts and law necessary for the board to deliberate and decide each case. The board's formal administrative hearing shall not be bound to strict rules of evidence.
- v. Admissibility. Admissibility of evidence and testimony shall be determined by the presiding hearing officer as provided by law.
- c. Closing Arguments. Closing arguments may be made by the licensee, either in proper person or by legal counsel, followed by closing arguments from the prosecuting legal or special counsel.
- d. Board Decision. The board's decision shall be based on finding(s) of fact and conclusion(s) of law. The board's decision shall be based on a preponderance of the evidence presented at a formal administrative hearing, together with the board's determination of appropriate sanctions, if any, by an affirmative majority record vote of the board members participating in the decision process. Decisions shall be recorded and made part of the record.
- e. Board Order. The board's order shall be rendered at the formal administrative hearing or taken under advisement and rendered within 30 days after the hearing and then served personally or domiciliary at the licensee's last known address by regular, registered, or certified mail, or by diligent attempt thereof.
- f. Finality of Board Order. The board's order shall become final and effective 11 days after licensee's receipt of the board's notice of its decision, provided an appeal is not filed.
- F. Complaint Dismissal. The board may, in its discretion and based upon insufficiency of evidence, orally dismiss a pending matter, or parts thereof, at a formal administrative hearing.
- G. Transcripts. A complete record of all formal administrative hearing proceedings shall be transcribed, maintained, and available upon written request for a minimum of three years after the date the pertinent board order is final. The board may require the advance payment of the appropriate fees to cover the cost of preparation of the requested transcript.
- H. Contempt. The failure of a licensee or witness to comply with a board order, after being duly served, constitutes contempt and the board may petition a court of competent jurisdiction to rule the witness or licensee in court to show cause why he should not be held in contempt of court.

#### I. Rehearing

- 1. An aggrieved licensee may file a motion for rehearing in proper form, within ten days, requesting reconsideration or a rehearing by the board or by the interlocutory hearing panel.
- 2. Grounds. The board or an interlocutory hearing panel may consider the motion for rehearing at the next regularly scheduled board meeting. The motion shall allege one or more of the following:
  - a. the board's decision was clearly contrary to the law or evidence;
  - b. newly discovered evidence not available at the time of the hearing which may be sufficient to reverse the board's decision;
  - c. issues not previously considered need to be examined; or
  - d. it is in the public's interest to reconsider the issues and the evidence.
- 3. Time. The board or the hearing officer shall grant or deny the motion for rehearing within 30 days after its submission.

- J. Judicial Review. An aggrieved licensee may appeal the board's decision to a court of competent jurisdiction within 30 days from the entry of the board order or the denial of the rehearing motion.
- K. Cease and Desist Orders; Injunctive Relief
  - 1. The board is empowered to issue an order to any person or facility engaged in any activity, conduct, or practice constituting a violation of the <u>R.S. 40:972</u> et seq. or the regulations promulgated thereto, directing such person or facility to forthwith cease and desist from such activity, conduct, or practice.
  - 2. If the person or facility to which the board directs a cease and desist order does not cease and desist the prohibited activity, conduct, or practice within the timeframe directed by said order, the board may seek, in any court of competent jurisdiction and proper venue, a writ of injunction enjoining such person or facility from engaging in such activity, conduct, or practice.
  - 3. Upon proper showing of the board such person or facility has engaged in the prohibited activity, conduct, or practice, the court shall issue a temporary restraining order prohibiting the person or facility from engaging in the activity, conduct, or practices complained of, pending the hearing on a preliminary injunction, and in due course a permanent injunction shall be issued after a contradictory hearing, commanding the cessation of the finally determined unlawful activity, conduct, or practices identified in the complaint.
- L. Reinstatement or Re-Issuance of CDS License.
  - 1. At any time after the suspension or revocation of a CDS license, the board may reinstate the license, but only at an official meeting of the board, after written notice, and by vote of an affirmative majority of the members of the board present and voting. In the event a license is reinstated or reissued following previously applied sanctions relative to a violation of this Chapter, said reinstatement or re-issuance shall have affixed thereto an attachment or addendum, specifically setting forth any restrictions placed upon said reinstated or reissued license by the board.
  - 2. In case of reinstatement, the reinstated licensee shall pay all applicable costs or fines, or both, and a reinstatement fee as provided for in the board's fee schedule established pursuant to R.S. 37:1184<sup>2</sup> and 40:972.
- M. Surrender of License
  - 1. Any person or facility holding a valid CDS license which ceases to engage in activity requiring a CDS license shall surrender said license to the board upon termination of this activity.
  - 2. Upon the surrender of said license, the person or facility shall forward all controlled substances and any unused order forms in his possession or under his control to the United States Drug Enforcement Administration as provided by federal laws and regulations.
  - 3. In the event a person or facility surrenders his DEA Registration to the DEA, then the person or facility shall surrender his CDS license immediately to the board.
  - 4. The acceptance of the voluntary surrender of a CDS license by the board shall result in the automatic suspension of the CDS license for an indefinite period of time.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2132 (October 2008).

## Subchapter C. Security Requirements

## §2713. General Requirements

- A. A licensee shall provide effective controls and procedures to guard against theft or diversion of controlled substances. In evaluating the overall security system of a licensee or applicant, the board may consider any of the following factors:
  - 1. the type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);
  - 2. the type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or nonusable powders);
  - 3. the quantity of controlled substances handled;
  - 4. the physical location of the premises;
  - 5. the type of building construction comprising the facility and the general characteristics of the building(s);
  - 6. the type of vault, safe, and secure enclosures or other storage system(s) used;
  - 7. the adequacy of key control systems, combination lock control systems, or both;
  - 8. the adequacy of electric detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources;

- 9. the extent of unsupervised public and visitor access to the facility including maintenance personnel and non-employee service personnel;
- 10. the adequacy of supervision of employee access;
- 11. local police protection or security personnel;
- 12. the adequacy for monitoring the receipt, manufacture, distribution, procurement, and disposition of controlled substances; and
- 13. the applicability of the security requirements contained in all federal, state, and local laws and regulations governing the management of waste.
- B. When physical security controls become inadequate, the physical security controls shall be expanded and extended accordingly.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2134 (October 2008).

# §2715. Physical Security Controls for Non-Practitioners, Narcotic Treatment Programs, and Compounders for Narcotic Treatment Programs

- A. Storage Areas
  - Schedules I and II. Raw materials, bulk materials awaiting further processing, and finished products
    which are controlled substances listed in Schedule I or II shall be stored in one of the following secure
    storage areas:
    - a. Where small quantities permit, a safe or steel cabinet:
      - i. which safe or steel cabinet shall have the following specifications or the equivalent: 30 manminutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
      - ii. which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way it cannot be readily removed; and
      - iii. which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the licensee, or such other protection as the board or its designee may approve.
    - b. a vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or
    - c. A vault constructed after September 1, 1971:
      - i. the walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with ½ inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;
      - ii. the door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
      - iii. which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;
      - iv. the walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the licensee, or such other protection as the board or its designee may approve, and, if necessary, alarm buttons at strategic points of entry to the perimeter area of the vault;
      - v. the door of which vault is equipped with contact switches; and
      - vi. which vault has one of the following: complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the board or its designee.
  - 2. Schedules III, IV and V. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV and V shall be stored in one of the following secure storage areas:
    - a. a safe or steel cabinet as described in this Section;

- b. a vault as described in this Section equipped with an alarm system as described in this Section;
- c. a building used for storage of Schedules III through V controlled substances with perimeter security which limits access during working hours and provides security after working hours and meets the following specifications:
  - i. has an electronic alarm system as described in this Section,
  - ii. is equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the licensee is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. Regarding hinged doors, where hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination or key lock type and:
    - (a) in the case of key locks, shall require key control which limits access to a limited number of employees, or;
    - (b) in the case of combination locks, the combination shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination;
- d. a cage, located within a building on the premises, meeting the following specifications:
  - i. having walls constructed of not less than No. 10 gauge steel fabric mounted on steel posts, which posts are:
    - (a) at least 1 inch in diameter;
    - (b) set in concrete or installed with lag bolts which are pinned or brazed; and
    - (c) placed no more than 10 feet apart with horizontal 1½ inch reinforcements every 60 inches:
  - ii. having a mesh construction with openings of not more than  $2\frac{1}{2}$  inches across the square;
  - iii. having a ceiling constructed of the same material, or in the alternative, a cage shall be erected which reaches and is securely attached to the structural ceiling of the building. A lighter gauge mesh may be used for the ceilings of large enclosed areas if walls are at least 14 feet in height;
  - iv. is equipped with a door constructed of No. 10 gauge steel fabric on a metal door frame in a metal door flange, and in all other respects conforms to all federal requirements; and
  - v. is equipped with an alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the licensee, or to such other source of protection as the board or its designee may approve;
- e. an enclosure of masonry or other material, approved in writing by the board or its designee as providing security comparable to a cage;
- f. a building or enclosure within a building which has been inspected and approved by DEA or its predecessor agency, the United States Bureau of Narcotics and Dangerous Drugs, and continues to provide adequate security against the diversion of Schedule III through V controlled substances, of which fact written acknowledgment has been made by the Special Agent in Charge of DEA for the area in which such building or enclosure is situated; or
- g. such other secure storage areas as may be approved by the board after considering the factors listed in §2713 of this Chapter.
- 3. Mixing of Schedules
  - a. Schedule III through V controlled substances may be stored with Schedules I and II controlled substances under security measures provided by this Section.
  - b. Non-controlled drugs, substances and other materials may be stored with Schedule III through V controlled substances in any of the secure storage areas required by this Section, provided that permission for such storage of non-controlled items is obtained in advance, in writing, from the special agent in charge of DEA for the area in which such storage area is situated. Any such permission tendered shall be upon the special agent in charge's written determination that such non-segregated storage does not diminish security effectiveness for Schedules III through V controlled substances.
- 4. Multiple Storage Areas. Where several types or classes of controlled substances are handled separately by the licensee or applicant for different purposes (e.g., returned goods, or goods in process), the controlled substances may be stored separately, provided each storage area complies with the requirements set forth in this Section.

5. Accessibility to Storage Areas. The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the licensee shall provide for adequate observation of the area by an employee specifically authorized in writing.

### B. Manufacturing and Compounding Areas

- 1. Before distributing a controlled substance to any person who the licensee does not know to be registered to possess the controlled substance, the licensee shall make a good faith inquiry, either with the DEA or the board, to determine that the recipient is registered to possess the controlled dangerous substance.
- 2. All manufacturing and compounding activities (including processing, packaging and labeling) involving controlled substances listed in any schedule shall be conducted in accordance with the following:
  - a. All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked. If security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the licensee.
  - b. Manufacturing activities with controlled substances shall be conducted in an area of clearly defined limited access under surveillance by an employee(s) designated in writing as responsible for the area. Limited access may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated responsible for the area may be engaged in the particular manufacturing operation being conducted, provided he is able to provide continuous surveillance of the area to ensure unauthorized individuals do not enter or leave the area without his knowledge.
  - c. During the production of controlled substances, the manufacturing areas shall be accessible only to those employees required for efficient operation. When employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors are present during production of controlled substances, the licensee shall provide for adequate observation of the area by an employee specifically authorized in writing.

#### C. Other Requirements/Narcotic Treatment Programs

- 1. Before distributing a controlled substance to any person who the licensee does not know to be registered to possess the controlled substance, the licensee shall make a good faith inquiry either with the DEA or the board to determine that the person is registered to possess the controlled substance.
- 2. The licensee shall design and operate a system to disclose to the licensee suspicious orders of controlled substances. The licensee shall inform the New Orleans Field Division Office of the DEA, or its successor, of suspicious orders when discovered by the licensee. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.
- 3. a. The licensee shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer:
  - i. without the prior written request of the customer;
  - ii. to be used only for satisfying the legitimate medical needs of patients of the customer; and
  - iii. only in reasonable quantities.
  - b. Such request shall contain the name, address, and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the licensee with other records of distribution of controlled substances. In addition, the procurement requirements of §2743 of this Chapter shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this Paragraph, the term "customer" includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.
- 4. When shipping controlled substances, a licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a licensee is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the licensee shall store controlled substances in a public warehouse which complies with the requirements set forth in §2715.A of this Chapter. In addition, the licensee shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

- 5. When distributing controlled substances through agents (e.g., sales representatives), a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled.
- 6. Before the initial distribution of carfentanil etorphine hydrochloride and/or diprenorphine to any person, the licensee shall verify that the person is authorized to handle the substances(s) by contacting the DEA.
- 7. The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual designated in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor
- 8. Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either:
  - a. the licensed practitioner;
  - b. a registered nurse under the direction of the licensed practitioner;
  - c. a licensed practical nurse under the direction of the licensed practitioner; or
  - d. a pharmacist under the direction of the licensed practitioner.
- 9. Persons enrolled in a narcotic treatment program shall be required to wait in an area physically separated from the narcotic storage and dispensing area. This requirement will be enforced by the program physician and employees.
- 10. All narcotic treatment programs shall comply with standards established by the department respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.
- 11. The board may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of patients enrolled in a program and the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security or requiring new security at a narcotic treatment program.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2135 (October 2008).

## §2717. Physical Security Controls for Practitioners and Pharmacies

- A. Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.
- B. Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.
- C. This Section shall also apply to non-practitioners authorized to conduct research or chemical analysis under another registration.
- D. Carfentanil, etorphine hydrochloride, and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.
- E. The licensee shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this Subsection, the term "for cause" includes surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.
- F. The licensee shall notify the board and the Field Division Office of the DEA in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The licensee shall also complete, and submit to the board and the Field Division Office of the DEA in his area, <a href="DEA Form 106">DEA Form 106</a>, or its electronic equivalent, regarding the loss or theft. When determining whether a loss is significant, a licensee should consider, among others, the following factors:
  - 1. the actual quantity of controlled substances lost in relation to the type of business;
  - 2. the specific controlled substances lost;
  - 3. whether the loss of the controlled substances can be associated with access to those controlled substances

- by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
- 4. a pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
- 5. whether the specific controlled substances are likely candidates for diversion;
- 6. local trends and other indicators of the diversion potential of the missing controlled substance.
- G. Whenever the licensee distributes a controlled substance (without being registered as a distributor, as permitted by law) he shall comply with the requirements imposed on non-practitioners.
- H. Central fill pharmacies shall comply with federal and state law when selecting private, common or contract carriers to transport filled prescriptions to a retail pharmacy for delivery to the ultimate user. When central fill pharmacies contract with private, common or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106 or its electronic equivalent. Retail pharmacies shall comply with federal and state law when selecting private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy. When retail pharmacies contract with private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery of such loss by use of a DEA Form 106 or its electronic equivalent.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2137 (October 2008).

## §2719. Security Controls for Freight Forwarding Facilities

- A. All Schedule II-V controlled substances that will be temporarily stored at the freight forwarding facility shall be either:
  - 1. stored in a segregated area under constant observation by designated responsible individual(s); or
  - 2. stored in a secured area that meets the requirements of this Chapter. For purposes of this requirement, a facility that may be locked down (i.e., secured against physical entry in a manner consistent with requirements of this Part) and has a monitored alarm system or is subject to continuous monitoring by security personnel will be deemed to meet the requirements of this Chapter.
- B. Access to controlled substances shall be kept to an absolute minimum number of specifically authorized individuals. Non-authorized individuals may not be present in or pass through controlled substances storage areas without adequate observation provided by an individual authorized in writing by the licensee.
- C. Controlled substances being transferred through a freight forwarding facility shall be packed in sealed, unmarked shipping containers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2138 (October 2008).

#### §2721. Employee Screening by Non-Practitioners

- A. An employer's comprehensive employee screening program shall include the following.
  - 1. Question. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.
  - 2. Question. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician or other authorized prescriber? If the answer is yes, furnish details.
  - 3. Advice. An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions shall be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person shall be advised that any false information or omission of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. The maintaining of fair employment practices, the protection of the person's right of privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2138 (October 2008).

# Subchapter D. Labeling and Packaging Requirements

# §2723. Symbol Required

- A. Each commercial container of a controlled substance shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, shall bear a label complying with the requirement of this Section.
- B. Each manufacturer shall print upon the labeling of each controlled substance distributed by him the symbol designating the schedule in which such controlled substance is listed.
- C. The following symbols shall designate the schedule corresponding thereto:

#### Schedule

Schedule I	CI or C-I
Schedule II	CII or C-II
Schedule III	CIII or C-III
Schedule IV	CIV or C-IV
Schedule V	CV or C-V

- The word "schedule" need not be used. No distinction need be made between narcotic and non-narcotic substances.
- D. The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through such carton or wrapper.
- E. The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing to an ultimate user.
- F. The symbol is not required on a commercial container containing, or on the labeling of, a controlled substance being utilized in clinical research involving blind and double blind studies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2138 (October 2008).

## §2725. Location and Size of Symbol on Label and Labeling

A. The symbol shall be prominently located on the label or the labeling of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance. The symbol on labels shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf. The symbol on all other labeling shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2139 (October 2008).

## §2727. Sealing of Controlled Substances

A. On each bottle, multiple dose vial, or other commercial container of any controlled substance, there shall be securely affixed to the stopper, cap, lid, covering, or wrapper or such container a seal to disclose upon inspection any tampering or opening of the container.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2139 (October 2008).

# §2729. Labeling and Packaging Requirements for Imported and Exported Controlled Substances

- A. The symbol requirements of this Section apply to every commercial container containing, and to all labeling of, controlled substances imported into the jurisdiction of and/or the customs territory of Louisiana.
- B. The symbol requirements of this Section do not apply to any commercial containers containing, or any labeling of, a controlled substance intended for export from Louisiana.
- C. The sealing requirements of this Section apply to every bottle, multiple dose vial, or other commercial container of any controlled substance listed in Schedule I or II, or any narcotic controlled substance listed in Schedule III or IV, imported into, exported from, or intended for export from, Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972. HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2139 (October 2008).

## Subchapter E. Recordkeeping Requirements

## §2731. General Information

- A. Persons Required to Keep Records and File Reports
  - Each licensee shall maintain the records and inventories and shall file the reports required by this Chapter, except as exempted by this Section. Any licensee who is authorized to conduct other activities without being registered to conduct those activities by federal law shall maintain the records and inventories and shall file the reports required by this Section for persons registered to conduct such activities. This latter requirement should not be construed as requiring stocks of controlled substances being used in various activities under one registration to be stored separately, nor does it require that separate records are required for each activity. Thus, when a researcher manufactures a controlled item, he shall keep a record of the quantity manufactured; when he distributes a quantity of the item, he shall use and keep invoices or order forms to document the transfer; when he imports a substance, he keeps as part of his records the documentation required of an importer; and when substances are used in chemical analysis, he need not keep a record of this because such a record would not be required of him under a registration to do chemical analysis. All of these records may be maintained in one consolidated record system. Similarly, the researcher may store all of his controlled items in one place, and every two years take inventory of all items on hand, regardless of whether the substances were manufactured by him, imported by him, or purchased domestically by him, of whether the substances will be administered to subjects, distributed to other researchers, or destroyed during chemical analysis.
  - 2. An individual practitioner is required to keep records of controlled substances in Schedules II, III, IV, and V which are dispensed, other than by prescribing or administering in the lawful course of professional practice.
  - 3. An individual practitioner is not required to keep records of controlled substances in Schedules II, III, IV, and V which are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual.
  - 4. An individual practitioner is not required to keep records of controlled substances listed in Schedules II, III, IV and V which are administered in the lawful course of professional practice unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges patients, either separately or together with charges for other professional services, for substances so dispensed or administered. Records are required to be kept for controlled substances administered in the course of maintenance or detoxification treatment of an individual.
  - 5. Each registered mid-level practitioner shall maintain in a readily retrievable manner those documents required by the state in which he practices which describe the conditions and extent of his authorization to dispense or distribute controlled substances and shall make such documents available for inspection and copying by authorized agents of the board. Examples of such documentation include protocols, practice guidelines or practice agreements.
  - 6. Licensees using any controlled substances while conducting preclinical research, in teaching at a registered establishment which maintains records with respect to such substances or conducting research in conformity with an exemption granted under Section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a registered establishment which maintains records in accordance with either of those sections, are not required to keep records if he notifies the DEA and the board of the name, address, and registration number of the establishment maintaining such records. This notification shall be given at the time the person applies for a CDS license or his renewal and shall be

- made in the form of an attachment to the application, which shall be filed with the application.
- 7. A distributing licensee who utilizes a freight forwarding facility shall maintain records to reflect transfer of controlled substances through the facility. These records shall contain the date, time of transfer, number of cartons, crates, drums or other packages in which commercial containers of controlled substances are shipped and authorized signatures for each transfer. A distributing licensee may, as part of the initial request to operate a freight forwarding facility, request permission to store records at a central location. Approval of the request to maintain central records would be implicit in the approval of the request to operate the facility. Otherwise, a request to maintain records at a central location shall be submitted in accordance with this Section. These records shall be maintained for a period of two years.
- 8. With respect to any and all records required by this Chapter which are maintained in a language other than English, the person responsible for maintaining such records shall provide a document accurately translating such records to English within 72 hours of such request by the board or an agent of the board.
- B. Maintenance of Records and Inventories
  - 1. Except as otherwise provided in this Section, every inventory and other records required to be kept under this Section shall be kept by the licensee and be available, for at least two years from the date of such inventory or records, for inspection and copying by authorized employees of the board.
    - a. Financial and shipping records may be kept at a central location, rather than at the registered location, if the licensee has notified the board in writing of his intention to keep central records. All notifications shall include the following:
      - i. the nature of the records to be kept centrally.
      - ii. the exact location where the records will be kept.
      - iii. the name, address, DEA registration number and type of DEA registration of the licensee whose records are being maintained centrally.
      - iv. whether central records will be maintained in a manual, or computer readable, form.
    - b. A pharmacy which possesses additional registrations for automated dispensing systems at long term care facilities may keep all records required by this Section for those additional registered sites at the pharmacy or other approved central location.
  - 2. All licensees authorized to maintain a central recordkeeping system shall be subject to the following conditions:
    - a. The records to be maintained at the central record location shall not include executed order forms, prescriptions and/or inventories which shall be maintained at each registered location.
    - b. If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the licensee shall provide access to such equipment with the records. If any code system is used (other than pricing information), a key to the code shall be provided to make the records understandable.
    - c. The licensee agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a written request from the board for such records, and if the board chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the board to inspect such records at the central location upon request by such employees without a warrant of any kind.
    - d. In the event that a licensee fails to comply with these conditions, the board may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the licensee without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorizations under this Paragraph the licensee shall, within the time specified by the board, comply with the requirements of this Section that all records be kept at the registered location.
  - 3. Licensees need not notify the board or obtain central recordkeeping approval in order to maintain records on an in-house computer system.
  - 4. ARCOS participants who desire authorization to report from other than their registered locations shall obtain a separate central reporting identifier. Request for central reporting identifiers shall be submitted to:

ARCOS Unit P.O. Box 28293 Central Station Washington, DC 20005

5. Each manufacturer, distributor, third-party logistics provider, importer, exporter, narcotic treatment program and compounder for narcotic treatment program shall maintain inventories and records of controlled substances as follows:

- a. inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all of the other records of the licensee; and
- b. inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the licensee or in such form that the information required is readily retrievable from the ordinary business records of the licensee.
- 6. Each individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in this Section.
- 7. Each pharmacy shall maintain the inventories and records of controlled substances as follows:
  - a. inventories and records of all controlled substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and
  - b. inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in a separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances. However, if a pharmacy employs an ADP system or other electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.
- C. Records of Authorized Central Fill Pharmacies and Client Pharmacies
  - 1. Every pharmacy that utilizes the services of a central fill pharmacy shall keep a record of all central fill pharmacies, including name, address and DEA number, which are authorized to fill prescriptions on its behalf. The pharmacy shall also verify the registration for each central fill pharmacy authorized to fill prescriptions on its behalf. These records shall be made available upon request for inspection by the board.
  - 2. Every central fill pharmacy shall keep a record of all pharmacies, including name, address and DEA number, for which it is authorized to fill prescriptions. The central fill pharmacy shall also verify the registration for all pharmacies for which it is authorized to fill prescriptions. These records shall be made available upon request for inspection by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972. HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2139 (October 2008), amended by the Department of Health, Board of Pharmacy, LR 46:570 (April 2020).

§2733. Inventory Requirements

- A. General Requirements. Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device shall be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the licensee, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the licensee, and substances in the possession of employees of the licensee and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in this Section. In the event controlled substances in the possession or under the control of the licensee are stored at a location for which he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and that option shall be indicated on the inventory.
- B. Initial Inventory Date. Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with this Section as applicable. In the event a person commences business with no controlled substances on hand, he shall record this fact as the initial inventory.

- C. Biennial Inventory Date. After the initial inventory is taken, the licensee shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.
  - 1. Exception
    - a. Pharmacies shall take a new inventory of all stocks of controlled substances on hand every year; the annual inventory may be taken on any date which is within one year of the previous annual inventory date.
    - b. Pharmacies shall take a new inventory on the following occasions:
      - i. arrival of a new pharmacist-in-charge;
      - ii. discovery of any substantial loss, disappearance, or theft of controlled substances;
      - iii. departure of a pharmacist-in-charge; and
      - v. permanent closure of a pharmacy.
- D. Inventories of Manufacturers, Distributors, Third-Party Logistics Providers, Dispensers, Researchers, Importers, Exporters, and Chemical Analysts. Each person registered or authorized to manufacture, distribute, dispense, import, export, provide logistics services, conduct research or chemical analysis with controlled substances and required to keep records shall include in the inventory the information listed below.
  - 1. Inventories of Manufacturers. Each person authorized to manufacture controlled substances shall include the following information in the inventory:
    - a. For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:
      - i. the name of the substance; and
      - ii. the total quantity of the substance to the nearest metric unit weight consistent with unit size.
    - b. For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:
      - i. the name of the substance:
      - ii. the quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and
      - iii. the physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.
    - c. For each controlled substance in finished form the inventory shall include:
      - i. the name of the substance:
      - ii. each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
      - iii. the number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and
      - iv. the number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).
    - d. For each controlled substance not included in this Section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compounding) the inventories shall include:
      - i. the name of the substance;
      - ii. the total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and
      - iii. the reason for the substance being maintained by the licensee and whether such substance is capable of use in the manufacture of any controlled substance in finished form.
  - 2. Inventories of Distributors and Third-Party Logistics Providers. Except for reverse distributors covered in this Section, each person authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to this Section.
  - 3. Inventories of Dispensers, Researchers, and Reverse Distributors. Each person authorized to dispense, conduct research, or act as a reverse distributor with controlled substances shall include in the inventory the same information required of manufacturers pursuant to this Section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser, researcher, or reverse distributor shall do as follows:
    - a. if the substance is listed in Schedule I or II, make an exact count or measure of the contents, or

- b. if the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he shall make an exact count of the contents.
- 4. Inventories of Importers and Exporters. Each person authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to this Section. Each such person who is also registered as a manufacturer or as a distributor shall include in his inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).
- 5. Inventories of Chemical Analysts. Each person authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to this Section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2141 (October 2008), amended by the Department of Health, Board of Pharmacy, LR 46:570 (April 2020).

## §2735. Continuing Records

- A. General Requirements
  - 1. Every licensee required to keep records pursuant to this Section shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him.
  - 2. Separate records shall be maintained by a licensee for each registered location except as provided in §2731.B. In the event controlled substances are in the possession or under the control of a licensee at a location for which he is not registered, the substances shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.
  - 3. Separate records shall be maintained by a licensee for each independent activity for which he is registered, except as provided in Subsection B of this Section.
  - 4. In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).
- B. Records for Manufacturers, Distributors, Third-Party Logistics Providers, Dispensers, Researchers, Importers, and Exporters
  - 1. Records for Manufacturers. Each person authorized to manufacture controlled substances shall maintain records with the following information:
    - a. For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or non-controlled substances in finished form:
      - i. the name of the substance;
      - ii. the quantity manufactured in bulk form by the licensee, including the date, quantity and batch or other identifying number of each batch manufactured;
      - iii. the quantity received from other persons, including the date and quantity of each receipt and the name, address, and registration number of the other person from whom the substance was received;
      - iv. the quantity imported directly by the licensee (under a registration as an importer) for use in manufacture by him/her, including the date, quantity, and import permit or declaration number for each importation;
      - v. the quantity used to manufacture the same substance in finished form, including:
        - (a) the date and batch or other identifying number of each manufacture;
        - (b) the quantity used in the manufacture;
        - (c) the finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);
        - (d) the number of units of finished form manufactured;

- (e) the quantity used in quality control;
- (f) the quantity lost during manufacturing and the causes therefore, if known;
- (g) the total quantity of the substance contained in the finished form;
- (h) the theoretical and actual yields; and
- (i) such other information as is necessary to account for all controlled substances used in the manufacturing process;
- vi. the quantity used to manufacture other controlled and non-controlled substances, including the name of each substance manufactured and the information required in Clause B.1.a.v of this Section;
- vii. the quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person to whom a distribution was made;
- viii. the quantity exported directly by the licensee (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exportation;
- ix. the quantity distributed or disposed of in any other manner by the licensee (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed; and
- x. the originals of all written certifications of available procurement quotas submitted by other persons as required by federal law relating to each order requiring the distribution of a basic class of controlled substance listed in Schedule I or II.
- b. For each controlled substance in finished form:
  - i. the name of the substance:
  - ii. each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
  - iii. the number of containers of each such commercial finished form manufactured from bulk form by the licensee, including the information required pursuant Clause B.1.a.v of this Section;
  - iv. the number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from whom the units were acquired;
  - the number of units of finished forms and/or commercial containers imported directly by the
    person (under a registration or authorization to import), including the date of, the number of
    units and/or commercial containers in, and the import permit or declaration number for, each
    importation;
  - vi. the number of units and/or commercial containers manufactured by the licensee from units in finished form received from others or imported, including:
    - (a) the date and batch or other identifying number of each manufacture;
    - (b) the operation performed (e.g., repackaging or relabeling);
    - (c) the number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes for such losses, if known; and
    - (d) such other information as is necessary to account for all controlled substances used in the manufacturing process;
  - vii. the number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed;
  - viii. the number of commercial containers exported directly by the licensee (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and
  - ix. the number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the licensee (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.
- Records for Distributors and Third-Party Logistics Providers. Each person authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to this Section.

- 3. Records for Dispensers and Researchers.
  - a. Each person authorized to dispense or conduct research with controlled substances shall maintain records with the same information required of manufacturers pursuant to this Section.
  - b. In addition, records shall be maintained of the number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser.
  - c. In addition to the requirements of this Paragraph, practitioners dispensing gamma-hydroxybutyric acid under a prescription shall also comply with federal law.
  - d. Pharmacies dispensing prescriptions for controlled substances shall use a dispensing information system of accurately recording partial fills and refills.
- 4. Records for Importers and Exporters. Each person authorized to import or export controlled substances shall maintain records with the same information required of manufacturers pursuant to this Section. In addition, the quantity disposed of in any other manner by the licensee (except quantities used in manufacturing by an importer under a registration as a manufacturer), which quantities are to be recorded pursuant to this Section; and the quantity (or number of units or volume in finished form) exported, including the date, quantity (or number of units or volume), and the export permit or declaration number for each exportation, but excluding all quantities (and number of units and volumes) manufactured by an exporter under a registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to this Section.

#### C. Records for Chemical Analysts

- 1. Each person authorized to conduct chemical analysis with controlled substances shall maintain records with the following information for each controlled substance:
  - a. the name of the substance;
  - b. the form or forms in which the substance is received, imported, or manufactured by the licensee (e.g., powder, granulation, tablet, capsule, or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.F., 10-milligram tablet or 10-milligram concentration per milliliter);
  - c. the total number of the forms received, imported or manufactured (e.g., 100 tablets, thirty 1-milliliter vials, or 10 grams of powder), including the date and quantity of each receipt, importation, or manufacture and the name, address, and DEA registration number, if any, of the person from whom the substance was received;
  - d. the quantity distributed, exported, or destroyed in any manner by the licensee (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation, or destruction, and the name, address, and DEA registration number, if any, of each person to whom the substance was distributed or exported.
- 2. Records of controlled substances used in chemical analysis or other laboratory work are not required.
- 3. Records relating to known or suspected controlled substances received as evidentiary material for analysis are not required by this Section.

### D. Records for Narcotic Treatment Programs

- 1. Each person authorized by federal and state law to maintain and/or detoxify controlled substance users in a narcotic treatment program shall maintain records with the following information for each narcotic controlled substance:
  - a. name of substance;
  - b. strength of substance;
  - c. dosage form;
  - d. date dispensed;
  - e. adequate identification of patient (consumer);
  - f. amount consumed;
  - g. amount and dosage form taken home by patient; and
  - h. dispenser's initials.
- 2. The records required by this Section will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with Subsection B of this Section.
- 3. All sites which compound a bulk narcotic solution from bulk narcotic powder to liquid for on-site use shall keep a separate batch record of the compounding.
- 4. Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by law.

- E. Records for Compounders for Narcotic Treatment Programs. Each person authorized to compound narcotic drugs for off-site use in a narcotic treatment program shall maintain records which include the following information:
  - 1. for each narcotic controlled substance in bulk form to be used in, or capable of use in, or being used in, the compounding of the same or other non-controlled substances in finished form:
    - a. the name of the substance;
    - b. the quantity compounded in bulk form by the licensee, including the date, quantity and batch or other identifying number of each batch compounded;
    - c. the quantity received from other persons, including the date and quantity of each receipt and the name, address and registration number of the other person from whom the substance was received;
    - d. the quantity imported directly by the licensee (under a registration as an importer) for use in compounding by him, including the date, quantity and import permit or declaration number of each importation:
    - e. the quantity used to compound the same substance in finished form, including:
      - i. the date and batch or other identifying number of each compounding;
      - ii. the quantity used in the compound;
      - iii. the finished form (e.g., 10-milligram tablets or 10-milligram concentration per fluid ounce or milliliter);
      - iv. the number of units of finished form compounded;
      - v. the quantity used in quality control;
      - vi. the quantity lost during compounding and the causes therefore, if known;
      - vii. the total quantity of the substance contained in the finished form;
      - viii. the theoretical and actual yields; and
      - ix. such other information as is necessary to account for all controlled substances used in the compounding process;
    - f. the quantity used to manufacture other controlled and non-controlled substances; including the name of each substance manufactured and the information required in Clause B.1.a.v of this Section;
    - g. the quantity distributed in bulk form to other programs, including the date and quantity of each distribution and the name, address and registration number of each program to whom a distribution was made;
    - h. the quantity exported directly by the licensee (under a registration as an exporter), including the date, quantity, and export permit or declaration number of each exploration; and
    - i. the quantity disposed of by destruction, including the reason, date and manner of destruction.
  - 2. for each narcotic controlled substance in finished form:
    - a. the name of the substance;
    - b. each finished form (e.g., 10-milligram tablet or 10 milligram concentration per fluid ounce or milliliter) and the number of units or volume or finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);
    - c. the number of containers of each such commercial finished form compounded from bulk form by the licensee, including the information required pursuant to Clause B.1.a.v of this Section;
    - d. the number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address and registration number of the person from whom the units were received;
    - e. the number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import permit or declaration number for, each importation;
    - f. the number of units and/or commercial containers compounded by the licensee from units in finished form received from others or imported, including:
      - i. the date and batch or other identifying number of each compounding;
      - ii. the operation performed (e.g., repackaging or relabeling);
      - iii. the number of units of finished form used in the compound, the number compounded and the number lost during compounding, with the causes for such losses, if known; and
      - iv. such other information as is necessary to account for all controlled substances used in the compounding process;
    - g. the number of containers distributed to other programs, including the date, the number of containers in each distribution, and the name, address and registration number of the program to which the containers were distributed;

- h. the number of commercial containers exported directly by the licensee (under a registration as an exporter), including the date, number of containers and export permit or declaration number for each exportation; and
- i. The number of units of finished forms and/or commercial containers destroyed in any manner by the licensee, including the reason, the date and manner of destruction.
- F. Additional Recordkeeping Requirements Applicable to Drug Products Containing Gamma-Hydroxybutyric Acid. In addition to the recordkeeping requirements for dispensers and researchers provided in this Chapter, practitioners dispensing gamma-hydroxybutyric acid manufactured or distributed in accordance with federal law shall maintain and make available for inspection and copying by the board, all of the following information for each prescription:
  - 1. name of the prescribing practitioner.
  - 2. prescribing practitioner's federal and state registration numbers, with the expiration dates of these registrations.
  - verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance.
  - 4. patient's name and address.
  - 5. patient's insurance provider, if available.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2142 (October 2008), amended by the Department of Health, Board of Pharmacy, LR 46:571 (April 2020), LR 49:681 (April 2023).

## §2737. Reports

- A. Reports from Manufacturers Importing Narcotic Raw Material
  - 1. Every manufacturer which imports or manufactures from narcotic raw material (opium, poppy straw, and concentrate of poppy straw) shall submit information which accounts for the importation and for all manufacturing operations performed between importation and the production in bulk or finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary or other recognized medical standards. Reports shall be signed by the authorized official and submitted in compliance with 21 CFR §1304.31 or its successor.
  - 2. The following information shall be submitted for each type of narcotic raw material (quantities are expressed as grams of anhydrous morphine alkaloid):
    - a. beginning inventory;
    - b. gains on reweighing;
    - c. imports;
    - d. other receipts;
    - e. quantity put into process;
    - f. losses on reweighing;
    - g. other dispositions; and
    - h. ending inventory.
  - 3. The following information shall be submitted for each narcotic raw material derivative including morphine, codeine, thebaine, oxycodone, hydrocodone, medicinal opium, manufacturing opium, crude alkaloids and other derivatives (quantities are expressed as grams of anhydrous base or anhydrous morphine alkaloid for manufacturing opium and medicinal opium):
    - a. beginning inventory;
    - b. gains on reweighing;
    - c. quantity extracted from narcotic raw material;
    - d. quantity produced/manufactured/synthesized;
    - e. quantity sold;
    - f. quantity returned to conversion processes for reworking;
    - g. quantity used for conversion;
    - h. quantity placed in process;
    - i. other dispositions;
    - j. losses on reweighing; and
    - k. ending inventory.
  - 4. The following information shall be submitted for importation of each narcotic raw material:
    - a. import permit number;
    - b. date shipment arrived at the United States port of entry;

- c. actual quantity shipped;
- d. assay (percent) of morphine, codeine and thebaine; and
- e. quantity shipped, expressed as anhydrous morphine alkaloid.
- 5. Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer in the manner and according to the method specified in the U.S. Pharmacopoeia. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.
- 6. Where factory procedure is such that partial withdrawals of opium are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.
- 7. All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it shall no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.
- B. Reports from Manufacturers Importing Coca Leaves
  - 1. Every manufacturer importing or manufacturing from raw coca leaves shall submit information accounting for the importation and for all manufacturing operations performed between the importation and the manufacture of bulk or finished products standardized in accordance with U.S. Pharmacopoeia, National Formulary, or other recognized standards. The reports shall be submitted in compliance with 21 CFR §1304.32.
  - 2. The following information shall be submitted for raw coca leaf, ecgonine, ecgonine for conversion or further manufacture, benzoylecgonine, manufacturing coca extracts (list for tinctures and extracts; and others separately), other crude alkaloids and other derivatives (quantities should be reported as grams of actual quantity involved and the cocaine alkaloid content or equivalency):
    - a. beginning inventory;
    - b. imports;
    - c. gains on reweighing;
    - d. quantity purchased;
    - e. quantity produced;
    - f. other receipts;
    - g. quantity returned to processes for reworking;
    - h. material used in purification for sale;
    - i. material used for manufacture or production;
    - losses on reweighing;
    - k. material used for conversion;
    - 1. other dispositions; and
    - m. ending inventory.
  - 3. The following information shall be submitted for importation of coca leaves:
    - a. import permit number;
    - b. date the shipment arrived at the United States port of entry;
    - c. actual quantity shipped;
    - d. assay (percent) of cocaine alkaloid; and
    - e. total cocaine alkaloid content.
  - 4. Upon importation of coca leaves, samples will be selected and assays made by the importing manufacturer in accordance with recognized chemical procedures. These assays shall form the basis of accounting for such coca leaves, which shall be accounted for in terms of their cocaine alkaloid content or equivalency or their total anhydrous coca alkaloid content. Where final assay data is not determined at the time of submission, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.
  - 5. Where factory procedure is such that partial withdrawals of medicinal coca leaves are made from individual containers, there shall be attached to the container a stock record card on which shall be kept a complete record of withdrawals therefrom.
  - 6. All in-process inventories should be expressed in terms of end-products and not precursors. Once precursor material has been changed or placed into process for the manufacture of a specified end-product, it shall no longer be accounted for as precursor stocks available for conversion or use, but rather as end-product in-process inventories.

#### C. Reports to ARCOS

- Reports generally. All reports required by this Subsection shall be filed with the ARCOS Unit, PO 28293, Central Station, Washington, DC 20005 on <u>DEA Form 333</u>, or on media which contains the data required by DEA Form 333 and which is acceptable to the ARCOS Unit. A copy of the report shall be filed with the board.
- 2. Frequency of Reports. Acquisition/Distribution transaction reports shall be filed every quarter not later than the fifteenth day of the month succeeding the quarter for which it is submitted; except that a licensee may be given permission to file more frequently (but not more frequently than monthly), depending on the number of transactions being reported each time by that licensee. Inventories shall provide data on the stocks of each reported controlled substance on hand as of the close of business on December 31 of each year, indicating whether the substance is in storage or in process of manufacturing. These reports shall be filed not later than January 15 of the following year. Manufacturing transaction reports shall be filed annually for each calendar year not later than January 15 of the following year, except that a licensee may be given permission to file more frequently (but not more frequently than quarterly).
- 3. Persons Reporting. For controlled substances in Schedules I, II or narcotic controlled substances in Schedule III and gamma- hydroxybutyric acid drug product controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repackage, label or relabel, and each person who is registered to distribute shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, and on each psychotropic controlled substance listed in Schedules III and IV as identified in Paragraph 4 of this Subsection.

#### 4. Substances Covered

- a. Manufacturing and acquisition/distribution transaction reports shall include data on each controlled substance listed in Schedules I and II and on each narcotic controlled substance listed in Schedule III (but not on any material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V), and on gamma-hydroxybutyric acid drug products listed in Schedule III. Additionally, reports on manufacturing transactions shall include the following psychotropic controlled substances listed in Schedules III and IV:
  - i. Schedule III
    - (a) benzphetamine;
    - (b) cyclobarbital;
    - (c) methyprylon; and
    - (d) phendimetrazine.
  - ii. Schedule IV
    - (a) barbital;
    - (b) diethylpropion (amfepramone);
    - (c) ethchlorvynol;
    - (d) ethinamate;
    - (e) lefetamine (SPA);
    - (f) mazindol;
    - (g) meprobamate;
    - (h) methylphenobarbital;
    - (i) phenobarbital;
    - (j) phentermine; and
    - (k) pipradrol.
- b. Data shall be presented in such a manner as to identify the particular form, strength, and trade name, if any, of the product containing the controlled substance for which the report is being made. For this purpose, persons filing reports shall utilize the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration.
- 5. Transactions Reported. Acquisition/distribution transaction reports shall provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the federal government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by government agencies). Manufacturing reports shall provide data on material manufactured, manufacture from other material, use in manufacturing other material and use

- in producing dosage forms.
- 6. Exceptions. A registered institutional practitioner who repackages or relabels exclusively for distribution or who distributes exclusively to (for dispensing by) agents, employees, or affiliated institutional practitioners of the licensee may be exempted from filing reports under this Section by applying to the ARCOS Unit of the DEA.
- D. Reports of Theft or Loss. The licensee shall notify the New Orleans Field Division Office of the DEA, or its successor, and the board, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of such theft or loss. The supplier is responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to Subsection E of this Section, within one business day of discovery of such theft or loss. The licensee shall also complete, and submit to the New Orleans Field Division Office of the DEA, or its successor, and the board, DEA Form 106, or its electronic equivalent, regarding the theft or loss. Thefts and significant losses shall be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action taken against them. When determining whether a loss is significant, a licensee should consider, among others, the following factors:
  - 1. the actual quantity of controlled substances lost in relation to the type of business;
  - 2. the specific controlled substances lost;
  - whether the loss of the controlled substances can be associated with access to those controlled substances
    by specific individuals, or whether the loss can be attributed to unique activities that may take place
    involving the controlled substances;
  - 4. a pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
  - 5. whether the specific controlled substances are likely candidates for diversion; and
  - 6. local trends and other indicators of the diversion potential of the missing controlled substance.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2145 (October 2008).

## Subchapter F. Production, Distribution, and Utilization

## §2739. Manufacture

- A. A licensee located in Louisiana engaged in the manufacture of controlled dangerous substances within Schedules I, II, III, IV, or V shall prepare a complete and accurate record of the date of manufacture, the theoretical and actual yields, the quantity used for quality control, the identity of batch numbers or other appropriate identification, and the quantity of any product reworked for any reason for each manufactured batch of controlled dangerous substances or each manufactured batch of drugs in which a controlled dangerous substance was used as a raw material.
- B. The licensee shall maintain manufacturing records in such a manner that the identity of a batch of controlled dangerous substances finished product can be matched to the identity of the controlled dangerous substance raw material used to make that product.
- C. The licensee shall maintain any other such records as are necessary to account for all controlled dangerous substances used in the manufacturing process.
- D. A building where manufacturing takes place shall be maintained in a clean and orderly manner and shall be of a suitable size, construction, and location to facilitate cleaning, maintenance, processing, and packing, labeling, or storing of legend drugs pursuant to federal and state requirements.
- E. All manufacturers shall employ security precautions by ensuring controlled access to premises to avoid drug diversion, including adequate legend drug storage, alarm system security, and adequate lighting and protection of the premises.
- F. Finished products, warehouse control, and distribution procedures shall include a system by which the distribution of each lot of drug can be readily determined to facilitate its recall if necessary. Records within the system shall contain the name and address of the consignee, date and quantity shipped, and the lot or control number of the drug. Records shall be retained a minimum of two years after the distribution of the drug has been completed, or for one year after the expiration date of the drug, whichever is longer.
- G. To assure the quality of the finished product, warehouse control shall include a system whereby the oldest approved stock is distributed first.

AUTHORITY NOTE: Promulgated in accordance with R.S.40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2147 (October 2008).

## §2741. Distribution

- A. A distributor or third-party logistics provider handling controlled substances in Schedules I or II shall maintain complete and accurate records of the original copies of all order forms received and filled for orders of controlled substances within these schedules. This file shall be kept separate from the licensee's other business and professional records and shall be kept in this file a minimum of two years from the date the order was filled.
- B. A distributor or third-party logistics provider handling controlled substances in Schedules III, IV, and V shall maintain complete and accurate records of all distributions for a minimum of two years from the date of each distribution. These records shall contain the full name, address, and registration number, if any, of the recipient, the common or established name of the controlled substance, its dosage, form, and strength, amount, and date of distribution.
- C. A distributor or third-party logistics provider shall not sell or distribute drugs or drug devices except to a person or facility authorized by law or regulation to procure or possess drugs or drug devices.
- D. A distributor or third-party logistics provider shall maintain and follow a written procedure to assure the proper handling and disposal of returned goods.
- E. A distributor or third-party logistics provider shall maintain a written policy for handling recalls and withdrawals of products due to:
  - 1. any voluntary action on the part of the manufacturer;
  - 2. the direction of the Food and Drug Administration, or any other federal, state, or local government agency; or
  - 3. replacement of existing merchandise with an approved product with a new package design.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2147 (October 2008), amended by the Department of Health, Board of Pharmacy, LR 46:571 (April 2020).

## §2743. Procurement Requirements

- A. Orders for Schedule I and II Controlled Substances
  - 1. General Requirements. A licensee acquiring controlled substances in Schedules I and II shall maintain a file of the duplicate copies of all order forms used to obtain controlled substances within these schedules. Each duplicate copy of any order form used to order controlled substances shall be kept in this file a minimum of two years from the date the order form was completed. This file shall be kept separate from the licensee's other business or professional records. These records shall contain the full name, address and license number of the supplier, the common or established name of the controlled substance, its dosage form and strength, the amount, and the date of receipt.
  - 2. DEA Form 222. Either a <u>DEA Form 222</u> or its electronic equivalent is required for each distribution of a Schedule I or II controlled substance except for the following:
    - a. distributions to persons exempted from registration by federal or state law;
    - b. exports from the United States that conform to federal requirements;
    - c. deliveries to a registered analytical laboratory or its agent approved by DEA;
    - d. delivery from a central fill pharmacy to a retail pharmacy.
  - 3. Electronic Orders
    - a. Electronic orders for Schedule I or II controlled substances shall comply with the federal requirements set forth in 21 CFR §1305.21 and §1311 or their successors.
      - i. To be valid, the purchaser shall sign an electronic order for a Schedule I or II controlled substance with a digital signature issued to the purchaser, or the purchaser's agent, by DEA as provided by federal law.
      - ii. The following data fields shall be included on an electronic order for Schedule I and II controlled substances:
        - (a) a unique number the purchaser assigns to track the order. The number shall be in the following 9-character format: the last two digits of the year, X, and six characters as selected by the purchaser.
        - (b) the purchaser's DEA registration number.
        - (c) the name of the supplier.
        - (d) the complete address of the supplier (may be completed by either the purchaser or the

- supplier).
- (e) the supplier's DEA registration number (may be completed by either the purchaser or the supplier).
- (f) the date the order is signed.
- (g) the name (including strength where appropriate) of the controlled substance product or the National Drug Code (NDC) number (the NDC number may be completed by either the purchaser or the supplier).
- (h) the quantity in a single package or container.
- i) the number of packages or containers of each item ordered.
- iii. An electronic order may include controlled substances that are not in schedules I and II and non-controlled substances.
- b. Procedure for Filling Electronic Orders
  - i. A purchaser shall submit the order to a specific supplier. The supplier may initially process the order (*e.g.*, entry of the order into the computer system, billing functions, inventory identification, etc.) centrally at any location, regardless of the location's registration with DEA. Following centralized processing, the supplier may distribute the order to one or more registered locations maintained by the supplier for filling. The licensee shall maintain control of the processing of the order at all times.
  - ii. A supplier may fill the order for a Schedule I or II controlled substance, if possible and if the supplier desires to do so and is authorized to do so under federal law.
  - iii. A supplier shall do the following before filling the order:
    - (a) Verify the integrity of the signature and the order by using software that complies with federal law to validate the order.
    - (b) Verify that the digital certificate has not expired.
    - (c) Check the validity of the certificate holder's certificate by checking the DEA's certificate revocation list.
    - (d) Verify the licensee's eligibility to order the controlled substances by checking the certificate extension data.
  - iv. The supplier shall retain an electronic record of every order, and, linked to each order, a record of the number of commercial or bulk containers furnished on each item and the date on which the supplier shipped the containers to the purchaser. The linked record shall also include any data on the original order that the supplier completes. Software used to process digitally signed orders shall comply with DEA's requirements digital certificates for electronic orders.
  - v. If an order cannot be filled in its entirety, a supplier may fill it in part and supply the balance by additional shipments within 60 days following the date of the order. No order is valid more than 60 days after its execution by the purchaser.
  - vi. A supplier shall ship the controlled substances to the registered location associated with the digital certificate used to sign the order.
  - vii. When a purchaser receives a shipment, the purchaser shall create a record of the quantity of each item received and the date received. The record shall be electronically linked to the original order and archived.
- B. Orders for Schedule III, IV, and V Controlled Substances. All licensees acquiring controlled substances in Schedules III, IV, or V shall maintain complete and accurate records of all order forms a minimum of two years from the date of each such receipt. These records shall contain the full name, address, and license number of the supplier, the common or established name of the controlled substance, its dosage form and strength, the amount and the date of receipt.
- C. Acquisition of Controlled Dangerous Substances by Institutional Facilities
  - 1. A Louisiana-licensed pharmacy in possession of a valid Louisiana CDS license and DEA registration may include a portion of its controlled dangerous substance inventory within an emergency drug kit (EDK) placed in a non-federally registered institutional facility, but only under the following conditions:
    - a. the EDK bears a valid EDK permit issued by the board; and
    - b. the inclusion and management of controlled dangerous substances in such EDK shall comply with the provisions of Section 1713.J of these rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2148 (October 2008), amended LR 39:313 (February 2013).

#### §2745. Prescriptions

- A. Practitioners Authorized to Issue Prescriptions. A prescription for a controlled substance may be issued only by an individual practitioner who is:
  - 1. authorized by law to prescribe controlled substances, and includes the following:
    - a. a physician;
    - b. a dentist;
    - c. a veterinarian;
    - d. a physician assistant;
    - e. an advanced practice registered nurse;
    - f. an optometrist;
    - g. a medical psychologist (but no narcotics);
  - 2. in possession of a valid license from the appropriate state professional licensing agency, and is not restricted by that agency from prescribing controlled substances; and
  - 3. in possession of a valid registration from the U.S. Drug Enforcement Administration (DEA), unless otherwise exempted from that registration requirement.

#### B. Purpose of Issue

- 1. A prescription for a controlled substance shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing of controlled substances rests upon the prescribing practitioner; however, a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the Controlled Substances Act (21 USC 829), and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
- 2. A prescription shall not be issued or dispensed in order for an individual practitioner to obtain controlled substances for supplying the individual for the purpose of general dispensing or administration to patients.
- 3. A prescription may not be issued for "detoxification treatment" or "maintenance treatment," unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the federal Food and Drug Administration (FDA) specifically for use in maintenance or detoxification treatment and the prescribing practitioner is in compliance with the federal rules governing such activities.

#### C. Manner of Issuance

- 1. All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued.
- 2. All prescriptions for controlled substances shall contain the following information:
  - a. full name and address of the patient;
  - b. drug name, strength and dosage form;
  - c. quantity of drug prescribed;
  - d. directions for use; and
  - e. name, address, telephone number and DEA registration number of the prescriber.
- 3. Repealed.
- 4. Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter, and they shall be manually signed by the prescriber.
  - a. The prescriptions may be prepared by the secretary or agent for the signature of the prescriber, but the prescriber is responsible in case the prescription does not conform in all essential respects to the law and regulations.
  - b. A corresponding liability rests upon the pharmacist who dispenses a prescription not prepared in the form prescribed by DEA regulations or these rules.
- 5. A prescriber exempted from registration under 21 CFR §1301.22(c) shall include on all such prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution, in lieu of the registration number of the practitioner required by this Section. Each such written prescription shall have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.
- 6. An official exempted from registration under 21 CFR §1301.23 shall include on all prescriptions issued by him his branch of service or agency and his service identification number, in lieu of the registration number of the practitioner required by this Section. Each such prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

- 7. Format Requirements. With the exception of medical orders written for patients in facilities licensed by the department, prescription forms shall adhere to the following requirements:
  - a. Written Prescriptions
    - i. The prescription form shall not be smaller than 4 inches by 5 inches, provided however, that forms used by pharmacists to record telephoned or transferred prescriptions shall be exempt from this requirement.
    - ii. The prescription form shall clearly indicate the authorized prescriber's name, licensure designation, address, telephone number, and DEA registration number. In the event multiple prescribers are identified on the prescription form, the prescriber's specific identity shall be clear and unambiguous. This identification may be indicated by any means, including but not limited to, a marked check box next to, or circling, the prescriber's printed name.
    - iii. The prescription form shall contain no more than four prescription drug or device orders. While nothing in these rules shall prohibit the pre-printing of any number of prescription drugs or devices on the prescription form, no prescription form issued by a prescriber shall identify more than four prescription drugs or devices to be dispensed.
    - iv. For each prescription drug or device ordered on a prescription form, there shall be a pre-printed check box labeled "Dispense as Written", or "DAW", or both.
    - v. For each prescription drug or device ordered on a prescription form, there shall be a refill instruction, if any.
    - vi. The prescription form shall bear a single printed signature line, and the prescriber shall manually sign the prescription.

#### b. Oral Prescriptions

- With the exception of prescriptions for controlled substances listed in Schedule II, a
  prescription issued by a prescriber may be communicated to a pharmacist by an employee or
  agent of the prescriber.
- ii. Upon the receipt of an oral prescription from a prescriber or his agent, the pharmacist shall reduce the order to a written form prior to dispensing the controlled substance.
- iii. The pharmacist shall record all of the information identified in this Subsection on the prescription form.

#### D. Practitioners Authorized to Dispense Prescriptions

- 1. A prescription for a controlled substance shall only be dispensed by a pharmacist, acting in the usual course of his professional practice, and either registered individually or employed in a registered pharmacy; however, nothing in this Section shall prohibit a physician, dentist, or veterinarian from personally dispensing such prescriptions to his own patients, in conformance with the laws and rules promulgated by the DEA and his own professional licensing agency.
- 2. Practitioners dispensing controlled substances shall procure and store those controlled substances in conformance with the requirements specified in this Chapter.
- Practitioners dispensing controlled substances shall dispense only those controlled substances which they
  have acquired through the procurement and distribution procedures described in this Chapter; a
  practitioner shall not dispense any controlled substances possessed by another practitioner.

#### E. Administering Narcotic Drugs

- 1. A practitioner may administer or provide directly, but not prescribe, a narcotic drug listed in any schedule to a narcotic dependent person for the purpose of maintenance or detoxification treatment if the practitioner meets both of the following conditions:
  - a. the practitioner is separately registered with the DEA as a narcotic treatment program; and
  - b. the practitioner is in compliance with DEA regulations regarding treatment qualifications, security, records, and unsupervised use of the drugs pursuant to federal law.
- 2. Nothing in this Subsection shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.
- 3. This Subsection is not intended to impose any limitations on a physician or authorized hospital staff to administer or provide narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or provide directly narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

- 4. A practitioner may prescribe, administer or provide directly any narcotic drug listed in Schedule III, IV, or V approved by the FDA specifically for use in maintenance or detoxification treatment to a narcotic dependent person if the practitioner complies with the requirements of 21 CFR.
- F. Controlled Substances Listed in Schedule II
  - 1. Requirements of Prescription
    - a. A pharmacist may dispense a controlled substance listed in Schedule II only pursuant to a written prescription, except as provided in Subparagraph F.1.f of this Section.
    - b. A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except for the following three circumstances:
      - i. a prescription prepared in conformance with Subsection C of this Section written for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile may serve as the original written prescription for purposes of this Subsection and it shall be maintained in accordance with §2731.B.7 of this Chapter.
      - ii. a prescription prepared in conformance with Subsection C of this Section written for a Schedule II substance for a resident of a long term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile may serve as the original written prescription for purposes of this Subsection and it shall be maintained in accordance with §2731.B.7 of this Chapter.
      - iii. a prescription prepared in conformance with Subsection C of this Section written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile, provided that the practitioner or practitioner's agent has noted on the prescription that the patient is a hospice patient. The facsimile may serve as the original written prescription for purposes of this Subsection and it shall be maintained in accordance with §2731.B.7 of this Chapter.
    - c. The original prescription shall be maintained in accordance with §2731.B.7 of this Chapter.
    - d. An individual practitioner may administer or provide directly a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to the provisions of Subsection E of this Section.
    - e. An institutional practitioner may administer or provide directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is provided for immediate administration to the ultimate user.
    - f. Authorization for Emergency Dispensing. An emergency situation exists when administration of the drug is necessary for immediate treatment, an appropriate alternate treatment is not available, and the prescribing practitioner cannot reasonably provide a written prescription. In the case of an emergency situation, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:
      - i. the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescriber);
      - ii. the prescription shall be immediately reduced to written form by the pharmacist and shall contain all information described in Paragraph C.2 of this Section, except for the signature of the prescriber;
      - iii. if the prescriber is not known to the pharmacist, he shall make a reasonable effort to determine that the oral authorization came from a registered prescriber, which may include a callback to the prescriber using his telephone number as listed in the telephone directory or other good faith efforts to insure his identity; and
      - iv. within seven days after authorizing an emergency oral prescription, the prescriber shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of Subsection C of this Section, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or

by mail, but if delivered by mail, it shall be postmarked within the seven day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to written form. The pharmacist shall notify the nearest office of the DEA if the prescriber fails to deliver a written prescription to him within the required time; failure of the pharmacist to do so shall void the authority conferred by this Paragraph to dispense without a written prescription of a prescriber.

- g. Central fill pharmacies shall not be authorized under this Paragraph to prepare prescriptions for a controlled substance listed in Schedule II upon receiving an oral authorization from a pharmacist or an individual practitioner.
- h. Notwithstanding the requirements of this Subsection, a prescription for a controlled substance listed in Schedule II may be generated, signed, transmitted or received in electronic form, but not until permitted by the DEA, and then only in conformance with the rules established for such procedures.
- 2. Expiration Date of Prescriptions. A prescription for a controlled substance listed in Schedule II shall expire 90 days after the date of issue. No pharmacist shall dispense any controlled substance pursuant to an expired prescription.
- 3. Refilling of Prescriptions; Issuance of Multiple Prescriptions
  - a. The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.
  - b. An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a controlled substance listed in Schedule II, provided the following conditions are met:
    - i. each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice;
    - the individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be dispensed immediately) indicating the earliest date on which a pharmacist may dispense each prescription;
    - iii. the individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;
    - iv. the individual practitioner complies fully with all other applicable requirements under federal law and these rules.
- G. Controlled Substances Listed in Schedules III, IV, and V
  - 1. Requirements of Prescription
    - a. A pharmacist may dispense a controlled substance listed in Schedule III, IV, or V which is a prescription drug only pursuant to either a written prescription signed by a practitioner or a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy, or in the alternative, to an oral prescription made by an individual practitioner and promptly reduced to written form by the pharmacist containing all the information required in Subsection C of this Section, except for the signature of the prescriber.
    - b. An individual practitioner may administer or provide directly a controlled substance listed in Schedule III, IV, or V without a prescription, in the course of his professional practice, subject to the provisions of Subsection E of this Section.
    - c. An institutional practitioner may administer or provide directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a written prescription signed by an individual practitioner, or pursuant to a facsimile of a written prescription or order for medication transmitted by the practitioner or the practitioner's agent to the institutional pharmacist, or pursuant to an oral prescription made by an individual practitioner and promptly reduced to written form by the pharmacist (containing all information required in Subsection C of this Section except for the signature of the prescriber), or pursuant to an order for medication made by an individual practitioner which dispensed for immediate administration to the ultimate user in conformance with the requirements of Subsection E of this Section.
    - d. A prescription issued by a prescriber may be communicated to a pharmacist by an employee or agent of the prescriber.
    - e. Notwithstanding the requirements of this Subsection, a prescription for a controlled substance listed in Schedule III, IV, or V may be generated, signed, transmitted or received in electronic form, but not until permitted by the DEA, and then only in conformance with the rules established for such procedures.

- 2. Expiration Date of Prescriptions
  - a. A prescription for a controlled substance listed in Schedule III or IV shall expire six months after the date of issue, or following the acquisition of the number of refills authorized by the prescriber on the original prescription, whichever shall first occur.
  - b. A prescription for a controlled substance listed in Schedule V shall expire one year after the date of issue, or following the acquisition of the number of refills authorized by the prescriber on the original prescription, whichever shall first occur.
  - c. No pharmacist shall dispense any controlled substance pursuant to an expired prescription.
- 3. Refilling of Prescriptions
  - a. The prescriber may authorize the refilling of a prescription for a controlled substance listed in Schedule III or IV by including specific refill instructions on the prescription prior to its issuance. The maximum number of refills the prescriber may authorize is five.
  - b. The prescriber may authorize the refilling of a prescription for a controlled substance listed in Schedule V by including specific refill instructions on the prescription prior to its issuance. There is no limitation on the number of refills the prescriber may authorize, subject however to the one year expiration date of the prescription.
  - c. In the absence of specific refill instructions on the original prescription from the prescriber, the prescription shall not be refilled.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2149 (October 2008), amended LR 41:685 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 42:1090 (July 2016), LR 47:1645 (November 2021), LR 49:1556 (September 2023).

#### §2747. Dispensing Requirements

- A. Location of Dispensing Activities. A pharmacist may dispense a prescription for a controlled substance pursuant to a valid prescription or order while in the usual course of his professional practice, but only within a prescription department in a pharmacy licensed by the board. A valid prescription or order is a prescription or order issued for a legitimate medical purpose by a practitioner authorized by law while acting in the usual course of his professional practice.
- B. Prescriptions for Controlled Substances Listed in Schedule II
  - 1. Oral Prescriptions. A pharmacist may accept and dispense an oral prescription from a prescribing practitioner, but only under the conditions described in, and in conformance with the requirements of, §2745.F.1.f of this Chapter.
  - 2. Prescriptions Received by Facsimile Equipment
    - a. The facsimile equipment designated for the receipt of prescriptions shall be located within a prescription department in a pharmacy. The paper or other media used in the facsimile equipment designated for the receipt of prescriptions shall be non-fading and technically capable of providing a legible prescription.
    - b. A pharmacist shall not dispense a prescription based solely on a copy of the prescription received by facsimile, except under the circumstances described in §2745.F.1.b.i, ii or iii.
    - c. In the event the facsimile transmission does not clearly identify the prescriber's office or other authorized location as the point of origin of the transmission, the pharmacist shall verify the authenticity of the prescription prior to dispensing the controlled substance.
  - 3. Expiration Date. A pharmacist shall not dispense a prescription for a controlled substance listed in Schedule II more than 90 days after the date of issue of the prescription.
  - 4. Completion of Prescription Form. In the event a pharmacist receives a prescription for a controlled substance listed in Schedule II lacking certain required information, the pharmacist may consult with the prescriber (but not the prescriber's agent) to clarify the prescriber's intent. Following a consultation with the prescriber and the appropriate documentation thereof on the prescription form:
    - a. a pharmacist may record changes to the following data elements on the prescription form:
      - i. patient's address;
      - ii. drug strength;
      - iii. quantity prescribed; or
      - iv. directions for use.
    - b. a pharmacist may add the following data elements on the prescription form:
      - i. patient's address;
      - ii. drug dosage form; or

- iii. prescriber's DEA registration number; however,
- c. a pharmacist shall never make changes to or add the following data elements on the prescription form:
  - i. patient's name;
  - ii. date of issue;
  - iii. drug name (except for generic interchange as permitted by law); or
  - iv. prescriber signature.
- 5. Partial Filling of Prescription
  - a. The partial filling of a prescription for a controlled substance listed in Schedule II is permissible with the following limitations:
    - i. When the pharmacist is unable to supply the full quantity called for in a written (or emergency oral) prescription, he shall make a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be dispensed within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescriber. No further quantity shall be dispensed beyond 72 hours without a new prescription.
    - ii. When a partial fill is requested by the patient or the prescriber, the pharmacist shall dispense a quantity less than the total quantity prescribed. The total quantity dispensed in all partial fillings shall not exceed the total quantity prescribed. No partial filling may be dispensed more than 30 days after the date on which the prescription was written. The requirement for a pharmacist to comply with a patient or prescriber request to dispense a partial fill shall not supersede the pharmacist's obligation relative to corresponding responsibility as described in Subsection E of this Section.
  - b. A prescription for a controlled substance listed in Schedule II written for a patient in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the prescriber prior to partially filling the prescription. Both the pharmacist and the prescriber have a responsibility to assure that the controlled substance is for a terminally ill patient.
    - i. The pharmacist shall record on the prescription form whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of these controlled substance rules.
    - ii. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.
    - iii. The total quantity dispensed in all partial fillings shall not exceed the total quantity prescribed.
    - iv. Notwithstanding the requirements of §2745.F.2, prescriptions for patients with a medical diagnosis documenting a terminal illness or for patients in a LTCF shall be valid for a period of time not to exceed 60 days from the date of issue unless terminated sooner by the discontinuance of the medication.
  - c. Information pertaining to current prescriptions for controlled substances listed in Schedule II for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:
    - i. output (display or printout) of the original prescription number, date of issue, identification of prescribing practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of the medication authorized (to include dosage, form, strength and quantity), listing of the partial fillings that have been dispensed under each prescription, and the information required in §2747.A.5.b.
    - ii. immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.
    - iii. retrieval of partially filled prescription information.
- 6. Refills. A pharmacist shall not refill a prescription for a controlled substance listed in Schedule II.
- 7. Labeling of Dispensed Medication and Filing of Prescription
  - a. The pharmacist dispensing a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a dispensing label containing the following data elements:

- i. name, address and telephone number of the pharmacy;
- ii. prescription number;
- iii. date of dispensing;
- iv. prescribing practitioner's name;
- v. patient's name;
- vi. drug name and strength;
- vii. directions for use;
- viii. pharmacist's name or initials;
- ix. the following warning statement: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed", provided however, that this statement shall not be required to appear on the label of a controlled substance dispensed for use in clinical investigations which are "blind."
- x. other cautionary or auxiliary labels as applicable.
- b. If the prescription is dispensed at a central fill pharmacy, the pharmacist at the central fill pharmacy shall affix to the package a label showing the name and address of the retail pharmacy and a unique identifier (i.e., the central fill pharmacy's DEA registration number) indicating the prescription was filled at the central fill pharmacy, as well as the data elements itemized above in Subsection B.7.a.
- c. The requirements of Subsection B.7.a shall not apply when a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized, provided that:
  - i. no more than a seven-day supply of the medication is dispensed at one time;
  - ii. the medication is not in the possession of the ultimate user prior to the administration;
  - iii. the institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of controlled substances listed in Schedule II; and
  - iv. the system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.
- d. After dispensing a prescription for a controlled substance listed in Schedule II, the pharmacist shall cancel the prescription by defacing the prescription form and recording his name or initials on the form.
- e. All written prescriptions and written records of emergency oral prescriptions shall be maintained in accordance with the requirements of §2731.B.7.
- 3. Provision of Prescription Information between Retail Pharmacies and Central Fill Pharmacies. Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall apply:
  - a. Prescriptions for controlled substances listed in Schedule II may be transmitted electronically from a retail pharmacy to a central fill pharmacy, including via facsimile. The retail pharmacy transmitting the prescription information shall:
    - record the words "CENTRAL FILL" on the face of the original prescription and record the name, address and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;
    - ii. ensure that all information required to be on a prescription pursuant to §2745.C is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);
    - iii. maintain the original prescription for a period of two years from the date the prescription was filled;
    - iv. keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.
  - b. The central fill pharmacy receiving the transmitted prescription shall:
    - i. keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address and DEA registration number of the retail pharmacy transmitting the prescription;
    - ii. keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist dispensing the prescription, and the date of dispensing of the prescription;
    - iii. keep a record of the date the dispensed prescription was delivered to the retail pharmacy and the method of delivery (private, common or contract carrier).

- C. Prescriptions for Controlled Substances Listed in Schedule III, IV, or V
  - 1. Oral Prescriptions. Upon the receipt of an oral prescription from a prescriber or his agent, the pharmacist shall immediately reduce the prescription information to written form. The pharmacist may then dispense the prescription and file the written record in his prescription files.
  - 2. Prescriptions Received by Facsimile Equipment
    - a. The facsimile equipment designated for the receipt of prescriptions shall be located within a prescription department in a pharmacy. The paper or other media used in the facsimile equipment designated for the receipt of prescriptions shall be non-fading and technically capable of providing a legible prescription.
    - b. The facsimile may serve as the original prescription form. After dispensing the prescription, the pharmacist shall file the facsimile prescription form in his prescription files.
    - c. In the event the facsimile transmission does not clearly identify the prescriber's office or other authorized location as the point of origin of the transmission, the pharmacist shall verify the authenticity of the prescription prior to dispensing the controlled substance.

#### 3. Expiration Date

- a. A prescription for a controlled substance listed in Schedule III or IV shall expire six months after the date of issue, or following the acquisition of the number of refills authorized by the prescriber on the original prescription, whichever shall first occur.
- b. A prescription for a controlled substance listed in Schedule V shall expire one year after the date of issue, or following the acquisition of the number of refills authorized by the prescriber on the original prescription, whichever shall first occur.
- c. No pharmacist shall dispense any controlled substances pursuant to an expired prescription.

#### 4. Refilling of Prescriptions

- a. No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times. No prescription for a controlled substance listed in Schedule V shall be filled or refilled more than one year after the date on which such prescription was issued.
- b. Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document. If entered on another document, such as a medication record, the document shall be uniformly maintained and readily retrievable. The following information shall be retrievable by the prescription number: name and dosage form of the controlled substance, the date filled or refilled, the quantity dispensed, initials of the dispensing pharmacist for each refill, and the total number of refills for that prescription. If the pharmacist merely initials and dates the back of the prescription, it shall be deemed that the full face amount of the prescription has been dispensed.
- c. As an alternative to the procedures described in Subparagraph C.4.b of this Section, an automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III, IV, and V, subject to the following conditions:
  - i. Any such proposed computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, and quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.
  - ii. Any such proposed computerized system must also provide on-line retrieval (via CRT display or hard-copy printout) of the current refill history for Schedule III, IV, or V controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.
  - iii. Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III, IV, or V controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy printout of each day's controlled substance orders refill data, that printout shall be verified, dated, and signed by the individual pharmacist

who refilled such a prescription order. The individual pharmacist shall verify that the data indicated is correct and then sign this document. This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data shall be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. The printout shall be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound logbook, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

- iv. Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name, or both). Such a printout shall include the name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the prescription number. In any computerized system employed by a user pharmacy, the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours. If the board or an agent of the board requests a copy of such printout from the user pharmacy, the pharmacy shall verify the printout transmittal capability of its system by documentation, e.g., postmark.
- v. In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy shall have an auxiliary procedure which will be used for documentation of refills on prescriptions for controlled substances listed in Schedule III, IV, or V. This auxiliary procedure shall insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.
- 5. Partial Filling of Prescriptions. When requested by the patient or prescriber, the pharmacist shall dispense a partial fill of a controlled substance listed in Schedules III, IV or V, provided that:
  - a. the information required for a partial filling, and the manner in which it is recorded, is the same as that required for a refill;
  - b. the number of partial fillings is not limited; however, the total quantity dispensed in all partial fillings shall not exceed the total quantity authorized on the original prescription. The total quantity authorized may be calculated as the sum of:
    - i. the quantity prescribed, and
    - ii. the calculated amount of the quantity prescribed times the number of refills originally authorized by the prescriber;
  - c. no dispensing shall occur more than six months after the date on which the prescription for a controlled substance listed in Schedule III or IV was issued, or more than one year after the date on which a prescription for a controlled substance listed in Schedule V was issued; and
  - d. the requirement for a pharmacist to comply with a patient or prescriber request to dispense a partial fill shall not supersede the pharmacist's obligation relative to corresponding responsibility as described in Subsection E of this Section.
- 6. Labeling of Medications and Filing of Prescriptions
  - a. The pharmacist dispensing a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a dispensing label containing the following data elements:
    - i. name, address and telephone number of the pharmacy;
    - ii. prescription number;
    - iii. date of dispensing;
    - iv. prescribing practitioner's name;
    - v. patient's name;
    - vi. drug name and strength;
    - vii. directions for use;
    - viii. pharmacist's name or initials;
    - ix. for controlled substances listed in Schedules III or IV, the following warning statement: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient

for whom it was prescribed", provided however, that this statement shall not be required to appear on the label of a controlled substance dispensed for use in clinical investigations which are "blind."

- x. other cautionary or auxiliary labels as applicable.
- b. If the prescription is dispensed at a central fill pharmacy, the pharmacist at the central fill pharmacy shall affix to the package a label showing the name and address of the retail pharmacy and a unique identifier (i.e., the central fill pharmacy's DEA registration number) indicating the prescription was filled at the central fill pharmacy, as well as the data elements itemized above in Subparagraph C.6.a of this Section.
- c. The requirements of Subparagraph C.6.a of this Section shall not apply when a controlled substance listed in Schedule III, IV, or V is prescribed for administration to an ultimate user who is institutionalized, provided that:
  - i. no more than a 34-day supply, or 100 dosage units, whichever is less, is dispensed at one time;
  - ii. the medication is not in the possession of the ultimate user prior to the administration;
  - iii. the institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of controlled substances listed in Schedule III, IV, and V; and
  - iv. the system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.
- d. After dispensing an original prescription for a controlled substance listed in Schedule III, IV, or V, the pharmacist shall record his name or initials on the form.
- e. All prescription forms shall be maintained in accordance with the requirements of Paragraph 2731.B.7 of this Chapter.
- 7. Transfer between pharmacies of prescription information for Schedule III, IV, or V for refill purposes
  - a. The transfer of prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization, whether or not the pharmacy from which the prescription is transferred is open for business. Transfers are subject to the following requirements.
    - i. The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:
      - (a) invalidation of the prescription;
      - (b) on the reverse of the invalidated prescription, the name, address, and DEA registration number of the pharmacy to which it was transferred, and the name of the pharmacist receiving the prescription information; and
      - (c) the date of the transfer and the name of the pharmacist transferring the information.
    - ii. The pharmacist receiving the transferred prescription information shall reduce to writing the following:
      - (a) indication of the transferred nature of the prescription;
      - (b) provide all information required for a prescription for a controlled substance (full name and address of the patient; drug name, strength, and dosage form; quantity prescribed and directions for use; and the name, address, telephone number, and DEA registration number of the prescribing practitioner) and include:
        - (i) date of issuance of original prescription;
        - (ii) original number of refills authorized on original prescription;
        - (iii) date of original dispensing;
        - (iv) number of valid refills remaining and date(s) and locations of previous refill(s);
        - (v) pharmacy's name, address, and DEA registration number and prescription number from which the prescription information was transferred;
        - (vi) name of pharmacist who transferred the prescription; and
        - (vii) pharmacy's name, address, and DEA registration number and prescription number from which the prescription was originally filled
    - iii. The original and transferred prescription(s) shall be maintained for a period of two years from the date of the last refill.
    - iv. Pharmacies electronically accessing the same prescription record shall satisfy all information requirements of a manual mode for prescription transferal.

- 8. Provision of Prescription Information between Retail Pharmacies and Central Fill Pharmacies.

  Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. The following requirements shall apply:
  - a. Prescriptions for controlled substances listed in Schedule III, IV, or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy, including via facsimile. The retail pharmacy transmitting the prescription information shall:
    - i. record the words "CENTRAL FILL" on the face of the original prescription and record the name, address and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;
    - ii. ensure that all information required to be on a prescription pursuant to Subsection 2745.C of this Chapter is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);
    - iii. indicate in the information transmittal the number of refills already dispensed and the number of refills remaining;
    - iv. maintain the original prescription for a period of two years from the date the prescription was last refilled; and
    - v. keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the retail pharmacy employee accepting delivery.
  - b. The central fill pharmacy receiving the transmitted prescription shall:
    - i. keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address and DEA registration number of the retail pharmacy transmitting the prescription;
    - ii. keep a record of the date of receipt of the transmitted prescription, the name of the pharmacist dispensing the prescription, and the dates of filling or refilling of the prescription;
    - iii. keep a record of the date the dispensed prescription was delivered to the retail pharmacy and the method of delivery (private, common or contract carrier).
- D. Dispensing Controlled Substances without a Prescription. A controlled substance listed in Schedule II, III, IV, or V which is not a prescription drug as determined under the <u>Federal Food, Drug, and Cosmetic Act</u> may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:
  - 1. such dispensing is made only by a pharmacist, and not by a non-pharmacist employee even if under the supervision of a pharmacist although after the pharmacist has fulfilled his professional and legal responsibilities, the actual cash, credit transaction, or delivery may be completed by a non-pharmacist;
  - 2. not more than 240 milliliters, or 8 ounces, of any such controlled substance containing opium, nor more than 120 milliliters, or 4 ounces, of any other such controlled substance, nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;
  - 3. the purchaser is at least 18 years of age;
  - 4. the pharmacist requires every purchaser of a controlled substance under this Paragraph not known to him to furnish suitable identification (including proof of age where appropriate);
  - 5. a bound record book for dispensing of controlled substances under this Paragraph is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the controlled substance to the purchaser; further, the book shall be maintained in conformance with the recordkeeping requirements identified in Paragraph 2731.B.7 of this Chapter;
  - 6. a prescription is not required for dispensing of the controlled substance pursuant to any federal or state law:
  - 7. central fill pharmacies may not dispense controlled substances to a purchaser at retail pursuant to this Paragraph.
- E. Professional Conduct. A license, registration, certification, permit, or any other credential deemed necessary to practice, or assist in the practice of, pharmacy may be subject to discipline when deviating from primary or corresponding responsibility to avert the following prohibited acts:
  - 1. Primary Responsibility.
    - a. drug diversion attempted, actual or conspired dispensing, distributing, administering, or manufacturing of a controlled substance not pursuant to a valid prescription or order while acting in the course of professional pharmacy practice is prohibited; or

- b. possession actual or conspired possession of a controlled substance not pursuant to a valid prescription or order issued for a legitimate medical purpose by an authorized practitioner in the usual course of professional practice.
- 2. Corresponding Responsibility.
  - a. Medical Purpose. The prescribing practitioner has the primary responsibility to issue a prescription for a controlled substance for a legitimate medical purpose, but a corresponding responsibility rests with the pharmacist or dispensing physician dispensing said prescription to ascertain that said prescription was issued for a legitimate medical purpose in the usual course of professional practice.
  - b. Authenticity. A pharmacist or dispensing physician shall exercise sound professional judgment to ascertain the validity of prescriptions for controlled substances. If, in the pharmacist's professional judgment, a prescription is not valid, said prescription shall not be dispensed.
- 3. Forged Prescriptions. It is unlawful to forge a prescription, or to dispense a forged prescription, for a controlled substance. The pharmacist or dispensing physician shall exercise professional diligence in determining the validity of a prescription as to the practitioner's authority and/or patient's identity, in order to prevent misrepresentation, fraud, deception, subterfuge, conspiracy, or diversion of controlled substances.
- 4. Altered Prescriptions. It is unlawful to personally alter a prescription, or to dispense an altered prescription, for a controlled substance, except as provided by §2747.B.4 of this Chapter.
- F. Accountability. The pharmacist-in-charge, the owner of a pharmacy permit, and/or other designated responsible parties, shall be accountable for shortages of controlled substances or inconsistencies indicated in an audit.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2152 (October 2008), LR 41:685 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 46:577 (April 2020), LR 47:1645 (November 2021), LR 49:681 (April 2023).

#### §2749. Disposal of Controlled Substances

- A. Any person in possession of any controlled substance and desiring or required to dispose of such substance may request assistance from the special agent in charge of the DEA in the area in which the person is located for authority and instructions to dispose of such substance. The request should be made as follows:
  - 1. if the person is a licensee, he shall list the controlled substance or substances which he desires to dispose of on DEA Form 41, and submit three copies of that form to the special agent in charge in his area; or
  - 2. if the person is not a licensee, he shall submit to the special agent in charge a letter stating:
    - a. the name and address of the person;
    - b. the name and quantity of each controlled substance to be disposed of;
    - c. how the applicant obtained the substance, if known; and
    - d. the name, address, and registration number, if known, of the person who possessed the controlled substances prior to the applicant, if known.
- B. The special agent in charge shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners:
  - 1. by transfer to person licensed by the board and authorized to possess the substance;
  - 2. by delivery to an agent of the DEA or to the nearest office of the DEA;
  - 3. by destruction in the presence of an agent of the DEA or other authorized person; or
  - 4. by such other means as the special agent in charge may determine to assure that the substance does not become available to unauthorized persons.
- C. In the event that a licensee is required regularly to dispose of controlled substances, the special agent in charge may authorize the licensee to dispose of such substances, in accordance with this Section, without prior approval of the DEA in each instance, on the condition that the licensee keep records of such disposals and file periodic reports with the special agent in charge summarizing the disposals made by the licensee. In granting such authority, the special agent in charge may place such conditions as he deems proper on the disposal of controlled substances, including the method of disposal and the frequency and detail of reports.
- D. When a patient or his designee wishes to return previously dispensed controlled dangerous substances to a pharmacy for disposal, the pharmacy shall inform the patient or his designee of the disposal mechanisms available to him. In the event the pharmacy elects to accept such previously dispensed products for disposal, the pharmacy shall comply with the following requirements:
  - 1. From the time of receipt of such products until the time of disposal, the pharmacy shall quarantine such products to keep them separate from its active dispensing stock and shall take appropriate security

- measures to prevent the theft or diversion of such products.
- 2. The pharmacy shall comply with the provisions of <u>21 CFR §1317</u> or its successor for the pharmacy's disposal of controlled substances.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2157 (October 2008), amended by the Department of Health, Board of Pharmacy, LR 46:794 (June 2020).

#### §2751. Distributions and Transfers of Controlled Substances

- A. Distribution by Dispenser to Another Practitioner or Reverse Distributor
  - 1. A dispenser may distribute (without being registered to distribute) a quantity of such controlled substance to:
    - a. another practitioner for the purpose of general dispensing by the practitioner to patients, provided that:
      - i. the receiving practitioner is authorized to dispense that controlled substance;
      - ii. the distribution is recorded by the dispenser and the receiving practitioner, in accordance with §2735.B of this Chapter;
      - iii. a DEA 222 order form is used as required for controlled substances listed in Schedule II; and
      - iv. the total number of dosage units of all controlled substances distributed by the dispenser pursuant to this Section during each calendar year shall not exceed 5 percent of the total number of dosage units distributed and dispensed by the dispenser during the same calendar year.
    - b. a reverse distributor who is authorized to receive such controlled substances.
  - 2. If, during any calendar year the dispenser has reason to believe the total number of dosage units of all controlled substances which will be distributed by him pursuant to this Section will exceed 5 percent of his total number of dosage units of all controlled substances distributed and dispensed by him during that calendar year, the dispenser shall obtain a license to distribute controlled substances.
  - 3. The distributions made by a retail pharmacy to automated dispensing systems at long term care facilities for which the retail pharmacy also holds registrations shall not count toward the 5 percent limit described in this Section.
- B. Distribution to Supplier, Third-Party Logistics Provider, or Manufacturer
  - 1. Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he obtained it or to the manufacturer of the controlled substance, or if designated, to the manufacturer's registered agent or accepting returns, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the controlled substance, the name, address, and DEA registration number, if any, of the person making the distribution, and the name, address, and DEA registration number of the supplier or manufacturer. In the case of returning a controlled substance listed in Schedule I or II, a DEA 222 order form shall be used and maintained as the written record of the transaction. Any person not required to register shall be exempt from maintaining the records required by this Section.
  - 2. Distributions referred to in this Subsection may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned, provided that prior arrangement has been made for the return and the person making the distribution delivers the controlled substance directly to an agent or employee of the person to whom the controlled substance is being returned.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2157 (October 2008), amended by the Department of Health, Board of Pharmacy, LR 46:571 (April 2020).

#### **Subchapter G. Administrative Procedures**

#### §2753. Inspections

A. The board may inspect any licensed facility or location of a licensed person including pertinent records for the purpose of determining compliance with the requirements of this Chapter and other state and federal laws and regulations related to controlled substances, subject to the limitations identified in <a href="R.S. 40:988(B)">R.S. 40:988(B)</a> and <a href="R.S. 40:988(C)">R.S. 40:988(C)</a>.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2158 (October 2008).

#### §2755. Seizures

A. The board may place under seal all drugs or devices that are owned by or in the possession, custody, or control of a licensee at the time his license is suspended or revoked, for a licensee's failure to timely renew his license, or at the time the board refuses to renew his license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2158 (October 2008).

#### §2757. Hearings

A. All formal administrative hearings conducted by the board shall be conducted in accordance with the Louisiana Administrative Procedures Act, R.S. 49:950, et seq., and §2711 of this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2158 (October 2008).

#### [End of Chapter 27]

#### Notes:

- <sup>1</sup> As a result of subsequent revisions, the correct citation for the definition of the term 'manufacturer' is now R.S. 40:961(26).
- <sup>2</sup> The statutory list of fees in R.S. 37:1184 is no longer current. The current list of fees is found in Chapter 1 of the administrative code, more specifically in Section 115. The board has not yet revised this Chapter to remove the obsolete citation.

#### **Chapter 29. Prescription Monitoring Program**

#### §2901. Definitions

A. As used in this Chapter, the following terms shall have the meaning ascribed to them unless the context clearly indicates otherwise:

*Delegate* – a person authorized by a prescriber or dispenser who is also an authorized user as described in Section 2917 of this Chapter to access and retrieve program data for the purpose of assisting the prescriber or dispenser, and for whose actions the authorizing prescriber or dispenser rains accountability.

Drugs of Concern – drugs other than controlled substances as defined by rule whose use requires tracking for public health purposes or which demonstrate a potential for abuse, including any material, compound, mixture, or preparation containing any quantity of the following substances, including its salts, esters, ethers, isomers, and salts of isomers [whenever the existence of such salts, esters, ethers, isomers, and salts of isomers is possible within the specific chemical designation]:

- a. butalbital.
- b. promethazine when present in oral liquid formulation.
- c. gabapentin

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1345 (July 2007), amended LR 36:755 (April 2010), effective September 1, 2010, LR 39:314 (February 2013), LR 40:1095, 1096 (June 2014), LR 41:684 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 45:42 (January 2019), LR 47:84 (January 2021), repromulgated LR 47:248 (February 2021), amended LR 50:390 (March 2024).

#### §2905. Advisory Council Open Meetings via Electronic Means

- A. Council Eligibility
  - 1. In accordance with <u>R.S. 42:17.4</u>, the council is eligible to conduct open public meetings via electronic means.
- B. Postings Prior to Meeting via Electronic Means
  - 1. At least 24 hours prior to the electronic meeting, the council shall provide the following, which shall be posted on the board's website, emailed to any member of the public or the news media who requests notice of meetings of the public body, and widely distributed to every known news media outlet that broadcasts or publishes news within the geographic area within the jurisdiction of the board:
    - a. the notice and agenda for the meeting;
    - b. detailed information regarding how members of the public may participate in the meeting and submit comments regarding matters on the agenda.
- C. Disability Accommodations
  - 1. Although an open meeting may be scheduled as in-person, nonetheless the council is obligated to provide for participation via electronic means on an individualized basis by people with disabilities.
  - 2. People with disabilities are defined as any of the following:
    - a. a member of the public with a disability recognized by the Americans with Disabilities Act (ADA);
    - b. a designated caregiver of such a person; or
    - c. a participant member of the agency with an ADA-qualifying disability.
  - 3. The board shall ensure that the written public notice for an open meeting, as required by <u>R.S. 42:19</u>, includes the name, telephone number and email address of the agency representative to whom a disability accommodation may be submitted.
  - 4. The designated agency representative shall provide the requestor with an accommodation, including the teleconference and/or video conference link, for participation via electronic means as soon as possible following receipt of the request, but no later than the start of the scheduled meeting.
  - 5. Participation via electronic means shall count for purposes of establishing quorum and voting.

AUTHORITY NOTE: Promulgated in accordance with R.S. 42:17.4.

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 50:1155 (August 2024).

#### §2911. Reporting of Prescription Monitoring Information

- A. Each dispenser shall submit to the board information regarding each prescription dispensed for a controlled substance or drug monitored by the program.
- B. Each dispenser shall submit the required information by electronic means no later than the next business day after the date of dispensing.

C. If the dispenser is unable to submit prescription information by electronic means, he may apply to the board for a waiver. The board may grant a waiver to that requirement; if so, the waiver shall state the format and frequency with which the dispenser shall submit the required information. The waiver shall expire one year after the date of issue, unless terminated sooner by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007), amended LR 39:314 (February 2013), LR 41:684 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 47:85 (January 2021), repromulgated LR 47:248 (February 2021).

#### §2913. Required Data Elements

- A. The information submitted for each prescription shall include data relative to the identification of the following elements of the transaction, or alternative data as identified in the board's program user manual. To the extent possible, the data shall be transmitted in the format established by the American Society for Automation in Pharmacy (ASAP) Telecommunications Format for Prescription Monitoring Programs Standard Version 4.2 or a successor.
  - 1. Prescriber information:
    - a. last and first name of prescriber;
    - b. United States Drug Enforcement Administration (DEA) registration number, and suffix if applicable, or in the alternative, the national provider identifier (NPI) number, as issued by the United States Centers for Medicare and Medicaid Services (CMS).
  - 2. Patient information:
    - a. last and first name of human patient and middle initial or name if available, or in the event of a veterinary prescription, the client's name and patient's animal species;
    - b. complete address of patient;
    - c. date of birth of patient;
    - d. identification number of patient;
    - e. gender code;
    - f. species code.
  - 3. Prescription information:
    - a. identification number of prescription;
    - b. date of issuance;
    - c. date of fulfillment;
    - d. number of refills authorized on original prescription and refill number;
    - e. method of payment for prescription (cash, insurance, or government subsidy).
  - 4. Drug information:
    - a. National Drug Code (NDC) number;
    - b. quantity dispensed;
    - c. days supply.
  - 5. Dispenser information:
    - a. DEA registration number, or in the alternative, the national provider identifier (NPI) number.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1346 (July 2007), amended LR 39:314 (February 2013).

#### §2914. Record Retention of Prescription Transaction Information

- A. The board shall retain a minimum of five years of prescription monitoring information for review by persons authorized to access such information.
- B. The board shall archive all prescription monitoring information not available for direct or indirect access up to 10 years.
- C. The board may remove and destroy prescription monitoring information in excess of 10 years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1006(G).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 47:85 (January 2021), repromulgated LR 47:248 (February 2021), amended LR 50:390 (March 2024).

#### §2915. Failure to Report Prescription Information

A. A dispenser who fails to submit prescription monitoring information to the board as required shall be referred to the appropriate professional licensing, certification, or regulatory agency for administrative sanctions as deemed appropriate by that agency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007).

#### §2917. Authorized Direct Access Users of Prescription Monitoring Information

- A. The following persons may access prescription monitoring information in the same or similar manner, and for the same or similar purposes, as those persons are authorized to access similar protected health information under federal and state law and regulation:
  - 1. persons authorized to prescribe or dispense controlled substances or drugs of concern, and their delegates, for the purpose of providing medical or pharmaceutical care for their patients, or for verifying their prescription records.
  - 2. designated representatives from the professional licensing, certification, or regulatory agencies of this state or another state charged with administrative oversight of those professionals engaged in the prescribing or dispensing of controlled substances or other drugs of concern.
  - 3. designated representatives from the Louisiana Medicaid program regarding Medicaid program recipients.
  - 4. designated representatives of the board or any vendor or contractor establishing or maintaining the prescription monitoring program.
  - 5. a medical examiner or coroner, or a delegate thereof, for the purpose of investigating an individual's death.
  - 6. a licensed substance abuse addiction counselor providing services as part of a state-licensed substance abuse or addiction treatment program.
  - 7. an epidemiologist with the Louisiana Department of Health for the purpose of assisting the board in analyzing prescription monitoring information in order to conduct public health evaluations to support public policy and education pursuant to an agreement with the board.
  - 8. prescription monitoring programs, electronic health information systems, and pharmacy information systems located in other states, territories, federal districts, and federal jurisdictions, through a secure interstate data exchange system approved by the board, but only in compliance with the provisions of R.S. 40:1007(G).

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007), amended LR 39:315 (February 2013), LR 40:1095 (June 2014), amended by the Department of Health, Board of Pharmacy, LR 47:85 (January 2021), repromulgated LR 47:248 (February 2021).

#### §2919. Registration Procedures for Authorized Direct Access Users

- A. Authorized users of prescription monitoring information, and their delegates, shall comply with the following requirements to register with the board, in order to receive the appropriate credentials to access prescription monitoring information.
  - 1. a. A prescriber or dispenser, excluding veterinarians, shall be automatically registered as a participant in the program and shall authenticate their identity through an online process in order to activate their account.
    - b. An agency applicant shall file an application with the program, using the form supplied by the program for that purpose.
  - 2. The board shall verify the prescriber or dispenser applicant is in possession of a valid license to prescribe or dispense controlled substances, or in the case of an agency applicant, the board shall verify agency representation
  - 3. Upon verification of all requirements, the board shall issue the appropriate credential necessary to access prescription monitoring information.
  - 4. Upon receipt of information that an authorized user no longer possesses authority to prescribe or dispense controlled substances, the program shall terminate the user's credentials to access prescription monitoring information. If or when the user's authority to prescribe or dispense controlled substances is reinstated, the program may reinstate the user's credentials to access prescription monitoring information.
  - 5. Prescribers and dispensers approved for access shall be responsible for the enabling and disabling of access privileges for their delegates, as well as the supervision of their activities.

AUTHORITY NOTE: Promulgated by R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007), amended LR 40:1095 (June 2014), amended by the Department of Health, Board of Pharmacy, LR 47:85 (January 2021), repromulgated LR 47:249 (February 2021).

### §2921. Methods of Access to Prescription Monitoring Information and Audit Trail Information

- A. Prescribers and dispensers, as well as their delegates, once properly registered, may solicit prescription monitoring information from the program concerning their patients, or for verifying their prescription records. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.
- B. Designated representatives from agencies charged with administrative oversight of prescribers and dispensers of controlled substances may solicit prescription monitoring information and audit trail information from the program concerning specific investigations of prescribers or dispensers. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.
- C. Designated representatives of the Louisiana Medicaid program, once properly registered, may solicit prescription monitoring information from the program concerning specific recipients. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.
- D. Designated representatives of the board, or any vendor or contractor establishing or maintaining the program, once properly registered, may solicit prescription monitoring information from the program for the purpose of establishing or maintaining the program's database.
- E. Upon receipt of one of the following methods of application by local, state, out-of-state, or federal law enforcement or prosecutorial officials, including judicially supervised specialty courts within the criminal justice system that are authorized by the Louisiana Supreme Court, the program may provide prescription monitoring information and audit trail information:
  - 1. a court order or court-ordered warrant, or a subpoena or summons issued by a judicial officer;
  - 2. a grand jury subpoena; or
  - 3. an administrative request, including an administrative subpoena or summons, a civil or an authorized investigative demand, or similar process authorized under law, provided by law enforcement to the board, and further, provided all of the following:
    - a. the information sought is relevant and material to a legitimate law enforcement inquiry;
    - b. the request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought;
    - c. de-identified information, or limited information that does not identify, or could not reasonably lead to the identification of an individual patient, could not reasonably be used.
- F. A medical examiner or coroner, or a delegate thereof, once properly registered, may solicit prescription monitoring information from the program for the purpose of investigating an individual's death. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.
- G. A licensed substance abuse addiction counselor, once properly registered, may solicit prescription monitoring information from the program for the purpose of providing services as part of a state-licensed substance abuse or addiction treatment program. The program may require such users to certify the legitimacy of their inquiry prior to furnishing the requested information.
- H. Upon receipt of an administrative request from a probation or parole officer, the program may provide prescription monitoring information. The probation or parole officer must certify the request for prescription monitoring information is for the purpose of monitoring an offender's compliance with participation in a drug diversion program or with other conditions of probation or parole related to monitored drugs.
- I. An epidemiologist with the Louisiana Department of Health, once properly registered, may solicit prescription monitoring information from the program for the purpose of assisting the board in analyzing prescription monitoring information in order to conduct public health evaluations to support public policy and education pursuant to an agreement with the board.
- J. Individuals may solicit their own prescription monitoring information and audit trail information from the program. To prevent inappropriate access to such information, the requestor shall personally appear at the program office and produce positive photo identification at the time of their request. The program shall furnish a single copy of the report responding to such request at no charge to the individual.
- K. A parent, legal guardian, or legal healthcare agent may solicit prescription monitoring information and audit trail information from the program for the purpose of reviewing the history of monitored drugs dispensed to a child or an individual for whom the agent makes healthcare decisions, to the extent consistent with federal and state confidentiality laws and regulations. To prevent inappropriate access to such information, the requestor shall personally appear at the program office and produce positive photo identification at the time of their

- request. The program shall furnish a single copy of the report responding to such request at no charge to the individual.
- L. An executor of a will or a court-appointed succession representative of an estate may solicit prescription monitoring information and audit trail information from the program for the purpose of reviewing the history of monitored drugs dispensed to a deceased individual. To prevent inappropriate access to such information, the requestor shall personally appear at the program office and produce positive photo identification at the time of their request. The program shall furnish a single copy of the report responding to such request at no charge to the individual.
- M. Program personnel, once properly registered, may solicit prescription monitoring information from the program's database for the purpose of maintaining the database, analysis and reporting of data, compliance reviews, and responding to legitimate inquiries from authorized users or other individuals.
- N. Prescription monitoring programs, electronic health information systems, and pharmacy information systems located in other states, territories, federal districts, and federal jurisdictions may access prescription monitoring information from the program through a secure interstate data exchange system or health information exchange system approved by the board, but only in compliance with the provisions of <u>R.S. 40:1007(G)</u>.
- O. The board may provide prescription monitoring information to authorized users of the prescription monitoring program via a state health information exchange or other third party conduit that has been approved by the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1347 (July 2007), amended LR 39:315 (February 2013), LR 40:1095 (June 2014), amended by the Department of Health, Board of Pharmacy, LR 47:86 (January 2021), repromulgated LR 47:249 (February 2021).

#### §2923. Unlawful Use or Disclosure of Prescription Monitoring Information

A. If the program receives evidence of inappropriate or unlawful use or disclosure of prescription monitoring information by an authorized user or his delegate, the program shall refer that user to the appropriate professional licensing, certification, or regulatory agency for administrative sanctions as deemed appropriate by that agency.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007), amended LR 40:1095 (June 2014).

#### §2925. Release of Prescription Monitoring Information to Other Entities

A. The program shall provide prescription monitoring information to public or private entities, whether located in or outside of the state, for public research, policy, or educational purposes, but only after removing information that identifies or could reasonably be used to identify prescribers, dispensers, and individual patients or persons who received prescriptions from prescribers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007), amended LR 39:315 (February 2013).

#### §2927. Legislative Oversight

A. The board shall report to the appropriate legislative oversight committee on a periodic basis, but in no case less than annually, the cost benefits and other information relevant to policy, research, and education involving controlled substances and other drugs of concern monitored by the program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007).

#### §2929. Program Evaluation

A. The board shall, in consultation with and upon recommendation of the advisory council, design and implement an evaluation component to identify cost benefits of the prescription monitoring program and other information relevant to policy, research, and education involving controlled substances and drug monitored by the prescription monitoring program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1011.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 33:1348 (July 2007).

[End of Chapter 29]

#### **Chapter 30. Pharmacy Benefit Managers**

#### §3003. Pharmacy Benefit Manager Permit

- A. A pharmacy benefit manager, as defined at <u>R.S. 40:2863</u>, shall obtain and maintain a pharmacy benefit manager permit from the board prior to conducting business in Louisiana if it administers, develops, maintains, performs, or provides one or more of the pharmacy services enumerated in <u>R.S. 40:2868</u> in the state or that affects one or more beneficiaries of a pharmacy benefit management plan, as defined at <u>R.S. 40:2863</u>, administered by the pharmacy benefit manager.
- B. A pharmacy benefit manager permit shall authorize the permit holder to administer pharmacy benefit management services.
- C. The board shall not issue a pharmacy benefit manager permit to any person or other entity which has not yet registered with the Louisiana Secretary of State to conduct business within the state.
- D. A pharmacy benefit manager permit is not transferable from the original owner. The permit shall not be subject to sale, assignment, or other transfer, voluntary or involuntary. Moreover, in the event the ownership of the pharmacy benefit manager changes by 50 percent or more after the initial issuance of the permit, the ownership will be deemed sufficiently different as to require a new pharmacy benefit manager permit. The continued operation of a pharmacy benefit manager permit after its ownership has changed by 50 percent or more shall constitute sufficient basis for the board to issue a finding for the operation of a pharmacy benefit manager without a valid permit, in violation of R.S. 40:2865.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1253. HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 47:591 (May 2021)

#### §3005. Permitting Procedures

- A. Application for Initial Issuance of Permit
  - 1. The board shall develop an application form suitable for the pharmacy benefit manager permit. The board may revise that application form on its own initiative in order to collect the information it deems necessary to properly evaluate an applicant.
  - 2. The application shall include copies of the following documents:
    - a. governance documents, including articles of incorporation, articles of association, partnership agreements, trade name certificates, trust agreements, shareholder agreements, and all amendments to such documents;
    - b. the applicant's standard generic contract template which it uses for contracts entered into by the applicant and pharmacies or pharmacy services administrative organizations in this state in the administration of pharmacy benefits for healthcare insurers, providers, or payors;
  - 3. The board shall not process applications received by facsimile, or that are incomplete, or submitted with the incorrect fee.
  - 4. Once received by the board, an application for the permit shall expire one year thereafter.
  - 5. In the event any information contained in the application or accompanying documents changes after being submitted to the board and before the issuance of the permit, the applicant shall immediately notify the board in writing and provide corrected information.
  - 6. The applicant may be required to personally appear before the board or any of its committees prior to any decision on the permit application.
  - 7. Upon approval of the application, the board shall issue the pharmacy benefit manager permit to the applicant.
- B. Application for Renewal of Permit
  - 1. All pharmacy benefit manager permits shall expire two years after the date of its initial issuance and the renewals shall expire every two years thereafter on that anniversary date.
  - 2. The board shall not process applications received by facsimile, or that are incomplete.
  - 3. In the event a pharmacy benefit manager does not submit a properly completed renewal application to the board prior to the expiration of the permit, the permit shall be rendered null and void. The continued operation of a pharmacy benefit manager with an expired permit shall constitute sufficient basis for the board to issue a finding for the operation of a pharmacy benefit manager without a valid permit, in violation of R.S. 40:2865.
  - 4. A pharmacy benefit manager permit not renewed by 30 days after the expiration date shall be automatically terminated by the board.
- C. Application for Reinstatement of Terminated, Suspended, or Revoked Permit
  - 1. The applicant shall complete the application form for this specific purpose supplied by the board.
  - 2. Upon receipt of a properly completed application form, the board staff shall refer the application to the

board's reinstatement committee for its consideration and shall notify the applicant of the time and place for the committee meeting.

#### D. Maintenance of Permit

- 1. A pharmacy benefit manager permit shall be valid for the entity to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary.
- 2. Upon receipt of a written request and payment of the fee authorized in R.S. 37:1184<sup>1</sup>, the board shall issue a duplicate or replacement permit to the applicant; however, such duplicate or replacement permit shall not serve or be used as an additional or second permit.

#### E. Permanent Closure of Permit

- 1. In the event the pharmacy benefit manager contemplates permanent closure of the pharmacy benefit manager business, the owner of the permit shall notify the board, in writing, 10 days prior to the anticipated date of closure and surrender its permit.
- 2. The notice required in this Subsection shall include an acknowledgement of the firm's obligation to maintain copies of all records for all patients and pharmacies in Louisiana for a minimum of two years following the date of closure and surrender of its permit, and further, the point of contact for all inquiries and requests for such records during that two-year period of time.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1253. HISTORICAL NOTE: Promulgated by the Department of Health, Board of Pharmacy, LR 47:591 (May 2021), amended LR 48:2105 (August 2022).

#### [End of Chapter 30]

#### Note:

The statutory list of fees in R.S. 37:1184 is no longer current. The current list of fees is found in Chapter 1 of the administrative code, more specifically in Section 115. The board has not yet revised Section 3005 to remove the obsolete citation.

#### Chapter 31. Illegal Payments; Required Disclosures of Financial Interests

#### Subchapter A. General Information

#### §3101. Scope and Purpose of Chapter

- A. Scope of Chapter. The rules of this Chapter interpret, implement, and provide for the enforcement of R.S. 37:1744 and R.S. 37:1745, or their successors, requiring disclosure of a pharmacist's financial interest in another health care provider to whom or to which the pharmacist refers a patient and prohibiting certain payments in return for referring or soliciting patients.
- B. Declaration of Purpose; Interpretation and Application. Pharmacists owe a fiduciary duty to patients to exercise their professional judgment in the best interests of their patients in providing, furnishing, recommending, or referring patients for health care items or services. The purpose of these rules and the laws they implement is to prevent payments by or to a pharmacist as a financial incentive for the referral of patients to a pharmacist or other health care provider for healthcare services or items. These rules shall be interpreted, construed, and applied so as to give effect to such purposes and intent.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2112 (October 2003), effective January 1, 2004, repromulgated LR 34:2158 (October 2008).

#### §3103. Definitions

A. As used in this Chapter, the following terms have the meaning ascribed to them by this Section: *Board* – the Louisiana Board of Pharmacy.

Financial Interest – a significant ownership or investment interest established through debt, equity, or other means and held, directly or indirectly, by a pharmacist or a member of a pharmacist's immediate family, or any form of direct or indirect remuneration for referral.

*Group Practice* – a group of two or more pharmacists and/or other health care providers legally organized as a general partnership, registered limited liability partnership, professional medical corporation, limited liability company, foundation, nonprofit corporation, faculty practice plan, or similar organization or association:

- a. in which each pharmacist who is a member of the group provides substantially the full range of services which the pharmacist routinely provides;
- b. for which substantially all of the services of the pharmacists who are members of the group are provided through the group and are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group;
- c. in which no pharmacist who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the pharmacist, except payment of a share of the overall profits of the group, which may include a productivity bonus based on services personally performed or services incident to such personally performed services, so long as the share of profits or bonus is not determined in any manner which is directly related to the volume or value of referrals by such pharmacist; and
- d. in the case of a faculty practice plan associated with a hospital, institution of higher education, or pharmacy school with an approved training program in which pharmacist members may provide a variety of different specialty services and provide professional services both within and outside the group, as well as perform other tasks such as research, solely with respect to services provided within such faculty practice plan.

*Health Care Item* – any substance, product, device, equipment, supplies, or other tangible good or article which is or may be used or useful in the provision of health care.

*Health Care Provider* – any person, partnership, corporation, or association licensed by a department, board, commission, or other agency of the state of Louisiana to provide, or which does in fact provide preventive, diagnostic, or therapeutic health care services or items.

*Immediate Family* – as respects a pharmacist, the pharmacist's spouse, children, parents, siblings, stepchildren, stepparents, in-laws, grandchildren, and grandparents.

*Investment Interest* – a security issued by an entity, including, without limitation, shares in a corporation, interests in or units of a partnership or limited liability company, bonds, debentures, notes, or other debt instruments.

Payment – transfer or provision of money, goods, services, or anything of economic value.

Person – as defined in R.S. 37:1164(33). or its successor.

Pharmacist – any individual currently licensed by the board to engage in the practice of pharmacy in the state of Louisiana.

*Pharmacy* – any place where drugs are dispensed and pharmacy primary care is provided.

*Referral* – any direction, recommendation, or suggestion given by a health care provider to a patient, directly or indirectly, which is likely to determine, control, or influence the patient's choice of another health care provider for the provision of health care services or items.

Remuneration for Referral – any arrangement or scheme, involving any remuneration, directly or indirectly, in cash or in kind, between a pharmacist, or an immediate family member of such pharmacist, and another health care provider that is intended to induce referrals by the pharmacist to the health care provider or by the health care provider to the pharmacist, other than any amount paid by an employer to an employee who has a bona fide employment relationship with the employer, for employment in the furnishing of any health care item or service. Significant Financial Interest – an ownership or investment interest shall be considered "significant", within the meaning of §3113, if such interest satisfies any of the following tests:

- a. Such interest, in dollar amount or value, represents 5 percent or more of the ownership or investment interests of the health care provider in which such interest is held; or
- b. Such interest represents 5 percent or more of the voting securities of the healthcare provider in which such interest is held.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2112 (October 2003), effective January 1, 2004, repromulgated LR 34:2158 (October 2008).

#### Subchapter B. Illegal Payments

#### §3105. Prohibition of Payments for Referrals

- A. A pharmacist or pharmacy shall not knowingly and willfully make, or offer to make, any payment, directly or indirectly, overtly or covertly, in cash or in kind, to induce another person to refer an individual to the pharmacist for the furnishing, or arranging for the furnishing, of any health care item or service.
- B. A pharmacist or pharmacy shall not knowingly and willfully solicit, receive, or accept any payment, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient to a health care provider for the furnishing, or arranging for the furnishing, of any health care item or service.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2159 (October 2008).

#### §3107. Prohibited Arrangements

A. Any arrangement or scheme, including cross-referral arrangements, which a pharmacist or pharmacy knows or should know has a principal purpose of ensuring or inducing referrals by the pharmacist to another health care provider, which, if made directly by the pharmacist or pharmacy would be a violation of §3113, shall constitute a violation of §3113.

AUTHORITY NOTE: Promulgated in accordance with R.S. 38:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2159 (October 2008).

#### §3109. Exceptions

- A. Proportionate Return on Investment. Payments or distributions by an entity representing a direct return on investment based upon a percentage of ownership, shall not be deemed a payment prohibited by R.S. 37:1745(B), or its successor, or §3105 of these regulations.
- B. General Exceptions. Any payment, remuneration, practice, or arrangement which is not prohibited by or unlawful under §1128(b) of the Federal Social Security Act (Act), 42 U.S.C §1320a-7b(b), or its successor, with respect to health care items or services for which payment may be made under Title XVIII or Title XIX of the Act, including those payments and practices sanctioned by the secretary of the United States Department of Health and Human Services, through the Office of the Inspector General, pursuant to §1128B(b)(3)(E) of the Act, through regulations promulgated at 42 CFR §1001.952, or its successor, shall not be deemed a payment prohibited by R.S. 37:1745(B), or its successor, or by §3105 of these rules with respect to health care items or services for which payment may be made by any patient or private or governmental payor.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated 34:2159 (October 2008).

#### §3111. Effect of Violation

A. Any violation of, or failure of compliance with, the prohibitions and provision of §3105 of this Chapter shall be deemed a violation of the Pharmacy Practice Act, <u>R.S. 37:1161</u> *et seq,* providing cause for the board to sanction a person culpable of such violation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2160 (October 2008).

#### Subchapter C. Disclosure of Financial Interests in Third-Party Health Care Providers

#### §3113. Required Disclosure of Financial Interest

A. Mandatory Disclosure. A pharmacist or pharmacy shall not make any referral of a patient outside the pharmacist's or pharmacy's group practice for the provision of health care items or services by another health care provider in which the referring pharmacist has a financial interest, unless, in advance of any such referral, the referring pharmacist or pharmacy discloses to the patient, in accordance with §3113 of this Chapter, the existence and nature of such financial interest.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2160 (October 2008).

#### §3115. Form of Disclosure

- A. Required Contents. The disclosure required by §3113 of this Chapter shall be made in writing, shall be furnished to the patient, or the patient's authorized representative, prior to or at the time of making the referral, and shall include:
  - 1. the pharmacist's or pharmacy's name, address, and telephone number;
  - 2. the name and address of the healthcare provider to whom the patient is being referred by the pharmacist or pharmacy;
  - 3. the nature of the items or services which the patient is to receive from the healthcare provider to which the patient is being referred; and
  - 4. the existence and nature of the pharmacist's or pharmacy's financial interest in the healthcare provider to which the patient is being referred.
- B. Permissible Contents. The form of disclosure required by §3113 of this Chapter may include a signed acknowledgment by the patient or the patient's authorized representative that the required disclosure has been given.
- C. Approved Form. Notice to a patient given substantially in the form of Disclosure of Financial Interest prescribed §3119 of this rule shall be presumptively deemed to satisfy the disclosure requirements of this Subchapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2113 (October 2003), effective January 1, 2004, repromulgated LR 34:2160 (October 2008).

#### §3117. Effect of Violation; Sanctions

- A. Effect of Violation. Any violation of, or failure of compliance with, the prohibitions and provision of §3113 of this chapter shall be deemed a violation of the Pharmacy Practice Act, <u>R.S. 37:1161</u> *et seq.*, providing cause for the board to sanction a pharmacist or pharmacy culpable of such violation.
- B. Administrative Sanctions. In addition to the sanctions provided for by R.S. 37:1241, upon proof of violation of §3113 by a pharmacist or pharmacy, the board may order that all or any portion of any amounts paid by a patient, and/or by any third-party payor on behalf of a patient, for health care items or services furnished upon a referral by the pharmacist or pharmacy in violation of §3113, be refunded by the pharmacist or pharmacy to such patient and/or third-party payor, together with legal interest on such payments at the rate prescribed by

law calculated from the date on which any such payment was made by the patient and/or third-party payors.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182. HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2114 (October 2003), effective January 1, 2004, repromulgated 34:2160 (October 2008).

#### §3119. Disclosure of Financial Interest

[Form begins at top of next page.]

# [Name of Pharmacist/Group] [Address] [Telephone Number]

# DISCLOSURE OF FINANCIAL INTEREST As Required by R.S. 37:1744 and LAC 46:LIII.3113-3115

ГО: DATE:	
(Name of Patient to Be Referred)	
(Patient Address)	
Louisiana law requires pharmacists and other health care providers to make certain disclosures to a patient whe refer a patient to another health care provider or facility in which the pharmacist has a significant financial interam/we are] referring you, or the named patient for whom you are legal representative, to:	
(Name and Address of Provider to Whom Patient is Referred)	
to obtain the following health care services, products, or items:	
(Purpose of the Referral)	
[I/we] have a financial interest in the health care provider to whom we are referring you, the nature and extwhich are as follows:	tent of
PATIENT ACKNOWLEDGEMENT	
I, the above-named patient, or legal representative of such patient, hereby acknowledge receipt, on the date independent of the described referral, of a copy of the foregoing Disclosure of Financial Interest.	licated
Signature of Patient or Patient's Representative)	
AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182. HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 29:2114 (Octobe 2003), effective January 1, 2004, repromulgated 34:2160 (October 2008).	T
[End of Chapter 31]	

#### Chapter 33. Severability

#### §3301. Severability

A. In the event any rule, sentence, clause, or phrase or any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof, and such remaining rules or portions thereof shall remain of full force and effect, as if such rule or portions thereof so determined, declared, or adjudged invalid or unconstitutional were not originally a part hereof. It is the intent of the Louisiana Board of Pharmacy to establish rules and regulations that are constitutional and enforceable so as to safeguard the health, safety, and welfare of the people of the State.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1182. HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 14:708 (October 1988), effective January 1, 1989, amended LR 29:2114 (October 2003), effective January 1, 2004, repromulgated LR 33:1348 (July 2007).

[End of Chapter 33]

[End of Part LIII of Title 46]

\* \* \*

[End of Louisiana Administrative Code]

#### About the Editor

Malcolm Broussard completed his pharmacy education in 1978 at Xavier University of Louisiana. He practiced pharmacy in the New Orleans area for 21 years in a variety of settings, including hospitals, chain and independent pharmacies as well as an ambulatory infusion center. The Louisiana Board of Pharmacy selected him to be their executive director in 1999. He served the Board in that role for 23 years.

During his tenure with the Board, Dr. Broussard drafted proposed legislation for the Board and provided testimony to legislative committees. He also drafted proposed rules for the Board and supervised the rule promulgation process. At the invitation of ULM and Xavier Colleges of Pharmacy, he was a guest lecturer on pharmacy law, and he delivered numerous pharmacy law continuing education programs to local, state, national and international pharmacy organizations. He edited the *Louisiana Pharmacy Law Book* published by the Board from 1999 to his retirement in 2022. Among other accomplishments, he also guided the Board through the development and implementation of both the state prescription monitoring program as well as the state medical cannabis program.

Dr. Broussard has been active in local, state, national and international pharmacy organizations. He has served in a leadership capacity for several organizations. He is a Past President of the Louisiana Pharmacists Association (LPA), the Louisiana Society of Health-System Pharmacists (LSHP), and the National Association of Boards of Pharmacy (NABP). He assisted Louisiana's health policy activities by serving as Chair of the Louisiana Commission on Preventing Opioid Abuse; he also represented the Board as a member of the Governor's Drug Policy Board.

Dr. Broussard is currently affiliated with Hygeia Solutions, LLC, a private consultancy for pharmacy credentialing and compliance issues.

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