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Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LIII. Pharmacists

Chapter 1. Introduction

§101. Preamble

A. Pursuant to the authority granted by R.S. 37:1182, 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 R.S. 37:1178, 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, R.S. 49:950 et seq., the Open Meetings Law, R.S. 42:4.1 et seq., and the Public Records Act, R.S. 44:1 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.

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.

§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 1/2” 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 Procedure Act

1. When the board approves a regulatory proposal for rulemaking, the board shall comply with the Administrative Procedure 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

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.

b. Pharmacy Technician

i. Application fee for new pharmacy technician certificate—$100.

ii. Certificate renewal fee, per year—$60.

iii. Delinquent renewal fee, per year (50 percent of renewal fee)—$30.

iv. Reinstatement fee for lapsed, suspended, or revoked certificate—$200.

c. Pharmacy Intern

i. Application fee for new pharmacy intern registration—$50.

d. Pharmacist

i. Application fee for new pharmacist license—$300.

ii. Application fee for transfer of pharmacist license—$150.

iii. License renewal fee, per year—$150.

iv. Delinquent renewal fee, per year (50 percent of renewal fee)—$75.

v. Reinstatement fee for lapsed, suspended, or revoked license—$200.

vi. Pharmacy education support fee, per year—$100.

2. Credentialing Fees for Businesses

a. Pharmacy

i. Application fee for new pharmacy permit—$500.

ii. Application fee for change of location of pharmacy permit—$200.

iii. Pharmacy permit renewal fee, per year—$200.

iv. Delinquent renewal fee for pharmacy permit, per year (50 percent of renewal fee)—$100.

v. Application fee for new controlled dangerous substance (CDS) license for pharmacy—$25.

vi. CDS license renewal fee, per year—$25.

vii. Delinquent renewal fee for CDS license, per year (50 percent of renewal fee)—$12.50

viii. Application fee for new emergency drug kit (EDK) permit—$50.

ix. EDK permit renewal fee, per year—$50.

x. Application fee for new automated medication system (AMS) registration—$150.

xi. AMS registration renewal fee, per year—$150.

xii. Application fee for new sterile compounding pharmacy permit—$500.

xiii. Sterile compounding pharmacy permit renewal fee, per year—$500.

xiv. Reinstatement fee for lapsed, suspended, or revoked pharmacy permit, CDS license, EDK permit, AMS registration, or sterile compounding pharmacy permit—$200.

xv. Pharmacy education support fee, per year—$100.

b. Durable Medical Equipment Provider

i. Application fee for new durable medical equipment (DME) permit—$200.

ii. DME permit renewal fee, per year—$200.

iii. Delinquent renewal fee for DME permit, per year (50 percent of renewal fee)—$100.

iv. Reinstatement fee for lapsed, suspended, or revoked DME permit—$200.

v. Pharmacy education support fee, per year—$100.

c. Pharmacy Benefit Manager

i. Application fee for new pharmacy benefit manager (PBM) permit—$500.

ii. PBM permit renewal fee, per year—$500.

iii. delinquent renewal fee for PBM permit, per year (50 percent of renewal fee)—$250.

3. Fees for Products and Services

a. Products

i. Pharmacist certificate—$75.

ii. Pharmacist silver certificate—$100.

iii. Louisiana Pharmacy Law Book—$40.

iv. Official list of licensees, per credential type—$150.

v. Photocopies of documents, per page—$0.50

b. Services

i. Administrative hearing fee—$250.

ii. Certification of credential—$20.

iii. Certification of practical experience to another jurisdiction—$25.

iv. Certification of document as true copy of office record—$5.

v. Handling and mailing, per page—$1.

4. Board member per diem, per day—$75.

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).

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, R.S. 37:1161 et seq., and the Administrative Procedure Act, R.S. 49:950 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 30 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.

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.

§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.

2. 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 based 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 R.S. 37:1241 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.

7. 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; and

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.

1. 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.

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.

§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

c. 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.

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 29:2079 (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, R.S. 49:950 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.

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.

§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.

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.

§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 a 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, 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, 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 and Advisory Opinions

A. The board may issue declaratory rulings in accordance with the Administrative Procedure Act, R.S. 49:950 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 Louisiana Pharmacy Practice Act 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).

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 at least 30 days prior to any examination. 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.

§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 the 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, 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 permanent licensure 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. *CPE Monitor*—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 R.S. 37:1241(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 to the applicant 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.

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.

§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.

AUHTORITY 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.:

1. 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.

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 29:2085 (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 administering medications to patients shall substantiate a violation of R.S. 37:1241(A)(3), 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:

1. 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.

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 29:2085 (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~~s~~ 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, R.S. 40:1001-1014, 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 management to be provided to the patient.

B. Registration

1. Eligibility

a. 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 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

a. 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.

c. 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 Louisiana Medical Practice Act. 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 health care 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 health care 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 medication 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).

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, 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.

i. 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 numbers 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, 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 intern 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 experience shall expire two years after the expiration date of the intern registration and shall no longer be valid for licensure purposes.

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, LR 26:2285 (October 2000), amended 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, R.S. 37:1161 et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1211.

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 to pharmacists shall be 1:1. However, the ratio of pharmacy interns on rotation with a board-approved college of pharmacy to pharmacists shall be no more than 3:1.

C. A pharmacy intern may not:

1. present or identify himself as a pharmacist;

2. sign or initial any document which is required to 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).

§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 violation 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).

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.

CPE Monitor—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 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 pharmacist 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 pharmacist 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 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 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.

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 47:245 (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 competencies.

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, and 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.

c. 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 fees.

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 to the applicant 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, 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 candidates to pharmacists on duty shall not exceed one to one at any given time.

2. The ratio of technicians to pharmacists on duty shall not exceed two to one at any given time. However, the ratio of technicians to pharmacists on duty may be increased to three to one if no technician candidates are on duty at the same time.

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).

§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 R.S. 37:1241(A)(2) 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, 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

1. A pharmacy technician 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).

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 prescriptions 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, LR 23:1310 (October 1997), amended 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 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 well-lighted, ventilated, 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. Drugs that require special storage shall be properly stored.

2. 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.

1. 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.

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 29:2087 (October 2003), effective January 1, 2004, LR 39:315 (February 2013), amended by Department of Health, Board of Pharmacy, LR 46:579 (April 2020), LR 47:1642 (November 2021), LR 48:497 (March 2022).

§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-in-charge.

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 the 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.

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 38:1239 (May 2012), amended by 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.

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).

§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.

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 27:2237 (December 2001), effective January 1, 2002, LR 29:2088 (October 2003), effective January 1, 2004, amended by 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 8 1/2 x 11 inches with the following wording in black letters at least 1 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 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 R.S. 40:964. 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), 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 21 CFR 1311 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~~s~~ 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~~s~~ 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~~s~~ 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 or 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:

a. 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. 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 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, amended 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 Department of Health.

2. If the demand is made by any other third party payor, the prescriber or pharmacy shall refer the demand to the Department 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

LOUISIANA UNIFORM PRESCRIPTION DRUG PRIOR AUTHORIZATION FORM

SECTION I - SUBMISSION

Submitted to:	Phone:	Fax:	Date:

SECTION II - PRESCRIBER INFORMATION

Last Name, First Name MI:		NPI# or Plan Provider #:	Specialty:	
Address:		City:	State:	ZIP Code:
Phone:	Fax:	Office Contact Name:	Contact Phone:	

SECTION III - PATIENT INFORMATION

Last Name, First Name MI:	DOB:	Phone:	☐ Male ☐ Female ☐ Other ☐ Unknown
Address:	City:	State:	ZIP Code:
Plan Name (if different from Section I):	Member or Medicaid ID #:	Plan Provider ID:	

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 - PRESCRIPTION DRUG INFORMATION

Requested Drug Name:						
Strength:	Dosage Form:	Route of Admin:	Quantity:	Days' Supply:	Dosage Interval/Directions for Use:	Expected Therapy Duration/Start Date:

To the best of your knowledge this medication is: _____New therapy/Initial request
_____Continuation of therapy/Reauthorization request

For Provider Administered Drugs only:

HCPCS/CPT-4 Code:_____NDC#:_____Dose Per Administration:_____

Other Codes:_____

Will patient receive the drug in the physician's office? ____Yes ____No

– If no, list name and NPI of servicing provider/facility: _____

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:	Date Diagnosed:

For pain-related diagnoses, pain is: _____Acute _____Chronic
For postoperative pain-related diagnoses: Date of Surgery_____

Pertinent laboratory values and dates (attach or list below):

Date	Name of Test	Value

SECTION VI - THIS SECTION FOR OPIOID MEDICATIONS ONLY

Does the quantity requested exceed the max quantity limit allowed? ___Yes ___No (If yes, provide justification below.)
Cumulative daily MME_____
Does cumulative daily MME exceed the daily max MME allowed? ___Yes ___No (If yes, provide justification below.)

	YES (True)	NO (False)		THE PRESCRIBER ATTESTS TO THE FOLLOWING:
SHORT AND LONG-ACTING OPIOIDS			A.	A complete **assessment** for pain and function was performed for this patient.
			B.	The patient has been **screened for substance abuse / opioid dependence**. (Not required for recipients in long-term care facility.)
			C.	The **PMP** will be accessed **each** time a controlled prescription is written for this patient.
			D.	A **treatment plan** which includes current and previous goals of therapy for both pain and function has been developed for this patient.
			E.	**Criteria** for failure of the opioid trial and for stopping or continuing the opioid has been established and explained to the patient.
			F.	**Benefits and potential harms** of opioid use have been discussed with this patient.
			G.	An **Opioid Treatment Agreement** signed by both the patient and prescriber is on file. (Not required for recipients in long-term care facility.)
LONG-ACTING OPIOIDS			H.	The patient requires continuous **around the clock** analgesic therapy for which alternative treatment options have been inadequate or have not been tolerated.
			I.	Patient previously utilized at least two weeks of short-acting opioids for this condition. Please enter drug(s), dose, duration and date of trial in pharmacologic/non-pharmacologic treatment section below.
			J.	Medication has **not** been prescribed to treat acute pain, mild pain, or pain that is not expected to persist for an extended period of time.
			K.	Medication has **not** been prescribed for use as an as-needed (PRN) analgesic.
			L.	Prescribing information for requested product has been **thoroughly reviewed** by prescriber.

IF NO FOR **ANY** OF THE ABOVE (A-L), PLEASE EXPLAIN:

SECTION VII - PHARMACOLOGIC & NON-PHARMACOLOGIC TREATMENT(S) USED FOR THIS DIAGNOSIS (BOTH PREVIOUS & CURRENT):

Drug name	Strength	Frequency	Dates Started and Stopped or Approximate Duration	Describe Response, Reason
Drug Allergies:			Height (if applicable):	Weight (if applicable):
Is there clinical evidence or patient history that suggests the use of the plan's pre-requisite medication(s), e.g. step medications, will be ineffective or cause an adverse reaction to the patient? ____Yes ____No (If yes, please explain in Section VIII below.)				

SECTION VIII - JUSTIFICATION (SEE INSTRUCTIONS)

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' section of the criteria specific to this request, if applicable.

Signature of Prescriber:_____ 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 Medical Examiners, LR 44:2155 (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.

3. 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 anticipated 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 DEA Form 222, or its successor. Alternatively, these drugs shall be inventoried on the DEA Form 41 (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 DEA Form 41, 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. The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises.

1. A change of ownership of a pharmacy is evident under the following conditions:

a. sale of a pharmacy;

b. death of a sole proprietor;

c. the addition or deletion of one or more partners in a partnership;

d. bankruptcy sale; or

e. a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

2. The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

3. Upon receipt of the new permit, the seller shall:

a. notify the board of the transaction, including the identity of the new owner(s); and

b. surrender the voided pharmacy permit and voided Louisiana Controlled Dangerous Substance License to the board.

4. Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(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 29:2092 (October 2003), effective January 1, 2004, amended LR 33:1131 (June 2007).

§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 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 pharmacy's 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 also 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 provision 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 security 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 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 medication 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 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).

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 R.S. 37:1164, 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 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.

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 R.S. 37:1241(A)(2) 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. 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.

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

1. 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 R.S. 37:1249.

2. The applicant shall complete an application form for this specific purpose supplied by the board and shall attach any documentation requested by the board and fees identified in R.S. 37:1184.

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:

1. 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 medications 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 26:1272 (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/or 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 the board's rules) of the personnel retrieving and administering the controlled substance 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 of the patient, or identification number for whom the drug was ordered;

f. identification of the certified pharmacy technician or pharmacist 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 by the Department of Health, Board of Pharmacy LR 40:2256 (November 2014), effective January 1, 2015, 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).

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.

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 14:708 (October 1988), effective January 1, 1989, amended LR 29:2093 (October 2003), effective January 1, 2004, LR 38:1235 (May 2012), amended by 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 Department of Health, Board of Pharmacy, LR 46:582 (April 2020), amended LR 46:793 (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 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 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 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 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 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.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 38:1235 (May 2012).

§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, LR 29:2093 (October 2003), effective January 1, 2004, amended 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, unused drugs may be returned to the pharmacy for re-dispensing 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 21 CFR §1317 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 U.S.C. §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 U.S.C. §13, 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.

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 the 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 hospital 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 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).

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 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 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 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;

8. 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 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 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 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 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 Department of Health, Board of Pharmacy, LR 46:584 (April 2020).

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, 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 Pharmacy Practice Act 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.

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), repromulgated 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, 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.

E. Maintenance of Permit

1. EDK permits are specific to a correctional center and to 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 federal Food and Drug Administration (FDA) requirements shall not be accepted for return or re-dispensed.

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).

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 be not 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.

d. 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.

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 Pharmacy Practice Act, 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 U.S.C. §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 U.S.C. §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. 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.

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, amended 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), amended 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-in-charge.

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 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 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.

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.

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), amended 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).

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;

l. 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 disease in humans or other animals; or

c. any substance other than food intended to affect the structure or any function of the body of humans or other animals.

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 is 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 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

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 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 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;

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 is 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 care giver:

a. instructions for use of the equipment;

b. safety precautions;

c. cleaning procedures;

d. maintenance procedures;

e. return demonstrations 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 care giver to comply with the prescription or medical order, and the ability of the patient or care giver to operate and clean the equipment as instructed.

D. Requirements for Providers of Other Durable Medical Equipment

1. Providers who sell, rent or furnish other 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:

i. 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:

a. 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 alternation, 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 NOTE: 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 permit shall expire 30 days thereafter. No person or other entity shall operate a 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 DEA Form 222, or its successor. Alternatively, these drugs shall be inventoried on the DEA Form 41 (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 DEA Form 41, 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 an authorized registrant, or destroyed.

3. Surrender of Credentials and Board Notice

a. 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 any and all 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, 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 procedures 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 41:2149 (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

1. 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 substance 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

A. Pursuant to Act 261 of the Regular Session of the 2015 Legislature as well as subsequent amendments, the Board of Pharmacy was directed to:

1. develop an annual, nontransferable specialty license for a pharmacy to dispense recommended marijuana for therapeutic use, to limit the number of such licenses to a maximum of 10, and to adopt rules regarding the geographical locations of dispensing pharmacies in the state; and

2. adopt rules relating to the dispensing of recommended marijuana for therapeutic use, with such rules to include, at a minimum, the following:

a. standards, procedures, and protocols for the effective use of recommended marijuana for therapeutic use as authorized by state law and related rules;

b. standards, procedures, and protocols for the dispensing and tracking of recommended therapeutic marijuana;

c. procedures and protocols to provide that no recommended therapeutic marijuana may be dispensed from, produced from, obtained from, sold to, or transferred to a location outside of this state;

d. standards, procedures, and protocols for determining the amount of usable recommended therapeutic marijuana that is necessary to constitute an adequate supply to ensure uninterrupted availability for a period of one month, including amount for topical treatments;

e. standards, procedures, and protocols to ensure all recommended therapeutic marijuana dispensed, with the exception of raw or crude marijuana product, is consistently pharmaceutical grade.

f. standards and procedures for the revocation, suspension, and nonrenewal of licenses;

g. other licensing, renewal, and operational standards deemed necessary by the Board of Pharmacy;

h. standards and procedures for testing recommended therapeutic marijuana samples for levels of tetrahydrocannabinols (THC) or other testing parameters deemed appropriate by the Board of Pharmacy;

i. standards for the protection of health, safety, and security for dispensers of recommended therapeutic marijuana;

j. standards for the licensure of dispensers of recommended therapeutic marijuana; and

k. standards for financial capacity to operate a marijuana pharmacy.

l. limitations on dispensing of raw or crude marijuana.

B. Marijuana is classified as a schedule I controlled substance by the U.S. Department of Justice, Drug Enforcement Administration.

1. As provided by the federal Controlled Substances Act, the procurement, possession, prescribing, distribution, dispensing, or administering of any schedule I controlled substance, including marijuana, is a violation of federal law.

2. Neither Louisiana law nor this Part can preempt federal law. Therefore, the provisions of this Subchapter notwithstanding, persons engaged in the activities described herein remain subject to the full force of federal law enforcement, including arrest and prosecution of criminal charges, the assessment of civil fines and forfeitures, as well as administrative consequences such as forfeiture of federal controlled substance registrations and exclusion from Medicare and other federal payer programs.

C. For the foregoing reasons, pharmacists and other persons credentialed by the board may wish to consult with their own legal counsel as well as any health care facility, private or governmental payor with which they are affiliated, professional liability insurers, and financial institutions with which they maintain depository relationships before engaging in the activities described herein.

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).

§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—all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of marijuana, excluding information of an educational nature designed to inform citizens of the nature and form of the state's therapeutic marijuana program and its legally permitted products.

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—a safe which conforms to or exceeds all of the following standards:

a. shall have the following specifications or the equivalent:

i. 30 man-minutes against surreptitious entry;

ii. 10 man-minutes against forced entry;

iii. 20 man-hours against lock manipulation; and

iv. 20 man-hours against radiological techniques;

b. 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

c. 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.

Approved Vault—

a. 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

b. a vault constructed after September 1, 1971:

i. the walls, floors, and ceilings of which are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one-half 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:

(a). thirty man-minutes against surreptitious entry;

(b). ten man-minutes against forced entry;

(c). twenty man-hours against lock manipulation; and

(d). twenty 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 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 responsibility 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 shall be equipped with one or more contact switches; and

vi. which vault has one of the following:

(a). complete electrical lacing of the walls, floor and ceiling;

(b). sensitive ultrasonic equipment within the vault;

(c). sensitive sound accumulator system; or

(d). such other device designed to detect illegal entry as may be approved by the board.

Board—the Louisiana Board of Pharmacy.

CFR—Code of Federal Regulations.

Deliver 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 percent 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—the Louisiana Department of Agriculture and Forestry.

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 per cent 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 21 CFR 111 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 approved by the commissioner of the Department of Agriculture and Forestry.

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—an individual currently licensed by the state Board of Medical Examiners to engage in the practice of medicine.

Prescription Monitoring Program (*PMP*)—the electronic prescription drug monitoring program established by R.S. 40:1001 et seq.

Producer—a person licensed by the Department of Agriculture and Forestry 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 Agriculture and Forestry 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 plan.

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).

§2443. Marijuana Products

A. Exclusive Source

1. The exclusive source of marijuana products shall be the producers licensed for that activity by the Department of Agriculture and Forestry (LDAF).

2. Licensed producers shall prepare pharmaceutical grade marijuana products as well as raw marijuana products for distribution to marijuana pharmacies licensed by the board.

3. Marijuana products from any other source shall be deemed misbranded and/or adulterated and shall not be distributed to any marijuana pharmacy, nor may such misbranded and/or adulterated products be dispensed by any marijuana pharmacy.

B. Laboratory Testing

1. Prior to manufacturing any marijuana product, the producer shall segregate all harvested marijuana into homogenized batches.

2. A producer shall make available each such batch at the production facility for testing by a laboratory approved by LDAF. The laboratory employee shall select a random sample from each such batch.

a. Medical marijuana concentrate shall not be used to produce any final product until it has passed all analysis limits for:

i. active ingredient analysis for characterization of potency;

ii. pesticide active ingredients, including but not limited to, the most recent list of targeted

pesticides published by LDAF;

iii. residual solvents;

iv. heavy metals; and

v. mycotoxins.

b. Product shall not be released for delivery to a marijuana pharmacy for sale or consumption until it has passed all concentrate analysis limits for:

i. microbiological contaminants;

ii. active ingredient analysis for accuracy of potency; and

iii. homogeneity.

c. Final products not produced from concentrate, e.g., dried and cured flower, shall not be released for delivery to a marijuana pharmacy for sale or consumption until it has passed all analysis limits for:

i. active ingredient analysis for characterization of potency;

ii. pesticide active ingredients, including but not limited to the most recent list of targeted pesticides published by LDAF;

iii. heavy metals;

iv. mycotoxins;

v. microbiological contaminants; and

vi. homogeneity.

d. LDAF personnel may select a random sample at any point in the process for the purpose of analysis for anything the LDAF deems necessary.

e. Samples shall be secured in a manner approved by LDAF at all times when not in immediate use for the analyses being conducted.

3. From the time that a batch of marijuana has been homogenized for sample testing and eventual packaging and sale to a pharmacy until the laboratory provides the results from its tests and analyses, the producer shall segregate and withhold from use the entire batch with the exception of the samples removed by the laboratory for testing. During this period of segregation, the producer shall maintain the marijuana batch in a secure, cool and dry location so as to prevent the marijuana from becoming contaminated or losing its efficacy. Under no circumstances shall a producer include marijuana in a marijuana product or sell it to a pharmacy prior to the time the laboratory has completed its testing and analysis and provided those results, in written or electronic form, to the producer or the producer's designated employee.

4. Testing Specifications

a. With respect to the microbiological test, a marijuana sample shall be deemed to have passed if it satisfies the recommended microbial and fungal limits for cannabis products as follows:

i. total yeast and mold: < 10,000 colony-forming units per gram (CFU/g); and

ii. E. coli (pathogenic strains) and Salmonella spp: < 1 CFU/g.

b. With respect to the mycotoxins test, a marijuana sample shall be deemed to have passed if it meets the following standards:

i. aflatoxin b1 < 20 parts per billion (ppb);

ii. aflatoxin b2 < 20 ppb;

iii. aflatoxin g1 < 20 ppb;

iv. aflatoxin g2 < 20 ppb; and

v. ochratoxin < 20 ppb.

c. With respect to the heavy metals test, a marijuana sample shall be deemed to have passed if it meets the following standards:

i. arsenic < 10 parts per million (ppm);

ii. cadmium < 4.1 ppm;

iii. lead < 10 ppm; and

iv. mercury < 2 ppm.

d. With respect to the pesticide chemical residue test, a marijuana sample shall be deemed to have passed if it does not contain any residues appearing on LDAF's approved list and any approved residues present are less than the limits allowed by LDAF.

e. With respect to the residual solvent test, a marijuana sample shall be deemed to have passed if the following solvents are below the listed limits:

i. butanes < 800 ppm;

ii. heptanes < 500 ppm;

iii. benzene < 1 ppm;

iv. toluene < 1 ppm;

v. hexanes < 10 ppm;

vi. total xylenes < 1 ppm; and

vii. ethanol < 5,000 ppm.

f. With respect to the test for homogeneity, a marijuana sample shall be deemed passed if each aliquot tested is within plus or minus 15 percent of the total aliquots average finding for potency for each labeled active ingredient. Any solid product will be considered not homogenous if 10 percent of the product contains more than 20 percent of the total active ingredient.

g. Every sample shall undergo an active ingredient analysis or potency analysis.

i. For medical marijuana concentrate samples, the potency test is to establish the presence of active ingredients and their concentrations for accurate calculations of amounts needed for the production of products. The analysis must identify the following substances:

(a). THC (tetrahydrocannabinol);

(b). THCA (tetrahydrocannabinolic acid);

(c). CBD (cannabidiol); and

(d). CBDA (cannabidiolic acid).

ii. For product samples, the potency test is to establish the active ingredient composition for verification of labeling to ensure accurate dosing. The maximum variance permitted is 15 percent from the labeled amount. For example, a product labeled as containing 10 milligrams of tetrahydrocannabinol (THC) shall contain no less than 8.5 milligrams THC and no more than 11.5 milligrams THC. For final products containing THCA, the total THC determined shall also be within the variance allowed for the THC as labeled.

5. Procedures for Sample Failures

a. In the event a medical marijuana concentrate sample fails testing for pesticides, heavy metals or mycotoxin, the entire batch from which the sample was taken shall be disposed of in accordance with the disposal rules promulgated by LDAF.

b. In the event a medical marijuana concentrate sample fails residual solvent testing, then, with prior approval of LDAF, the product may be subjected to an

appropriate remedy, e.g., vacuum drying, reformulated and tested again. The reformulation must pass all required tests for a medical marijuana concentrate in duplicate before it can be released for use in products. If either duplicate fails any test, the entire batch shall be disposed of in accordance with the disposal rules promulgated by LDAF. A batch of medical marijuana concentrate can only be reformulated once and only to remedy excessive residual solvents.

c. In the event a product fails the microbiological testing, the entire batch from which the sample was taken shall be disposed of in accordance with the disposal rules promulgated by LDAF.

d. In the event a product fails the potency or homogeneity testing, then, with prior approval of LDAF, the product can be re-sized and tested again. The reformulated product shall be tested again in duplicate and pass all required tests before it can be released for sale or consumption. If either duplicate fails any test, the entire batch shall be disposed of in accordance with the disposal rules promulgated by LDAF.

6. In the event of any test failure, the laboratory shall transmit to LDAF an electronic copy of such test result at the same time it transmits those results to the producer. In addition, the laboratory shall maintain the laboratory test results including all relevant chromatograms and quality control documentation for at least five years and make them available to LDAF at its request.

7. The laboratory shall dispose of any remaining medical marijuana concentrate or product samples no sooner than 60 days following the completion of any testing, in compliance with the disposal rules promulgated by LDAF.

8. A producer shall provide the laboratory test results to the marijuana pharmacy for each batch of marijuana used in a product acquired by the marijuana pharmacy. The pharmacy shall make such testing results available upon request to their patients, caregivers, and physicians who recommended such marijuana products dispensed to their patients.

C. Product Dosage Forms

1. The producer shall limit their production 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. bulk raw product.

2. The producer may produce 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 by the commissioner of LDAF.

4. Any marijuana product not in compliance with the provisions of this Section shall be deemed adulterated.

D. Packaging and Labeling Requirements

1. Packaging

a. The producer shall ensure every product intended for dispensing to a patient is placed within a child-resistant, light-resistant, tamper-evident container prior to sale or transport to the pharmacy.

i. A package shall be deemed child-resistant if it satisfies the standard for ‘special packaging’ as set forth in the United States Consumer Product Safety Commission’s “poison prevention packaging” as found in 16 CFR 1700.1(b)(4) or its successor.

ii. A package shall be deemed light-resistant if it satisfies the standard set forth in chapter 671, “containers: performance testing,” of the *United States Pharmacopeia* (*USP*).

iii. A package shall be deemed tamper-evident if it clearly indicates prior access to the container.

b. Packaging selected by the producer shall be subject to the following restrictions:

i. shall not specifically target individuals under the age of 18 years;

ii. shall not bear any resemblance to a trademarked, characteristic or product-specialized packaging of any commercially available candy, snack, baked good or beverage;

iii. shall not use the words "candy" or "candies";

iv. shall not use a cartoon, color scheme, image, graphic or feature that might make the package attractive to children; and

v. shall not use a seal, flag, crest, coat of arms or other insignia that could reasonably lead any person to believe the product has been endorsed, manufactured by, or used by any state, parish, municipality, or any agent thereof.

2. Labeling

a. Each product shall be labeled by the producer prior to its sale to the marijuana pharmacy.

b. Each label shall be securely affixed to the package and shall comply with labeling standards for marijuana products promulgated by LDAF.

c. The label for each product shall bear a product identification code registered with the board.

d. The producer may utilize a two-dimensional quick response (QR) code or a package insert which is enclosed or attached to the product container to provide the information required in this Section. If the producer elects to use such supplementary labeling, the label affixed to the outer surface of the product container shall contain the following information, at a minimum:

i. the batch or lot number;

ii. the potency of any THC or CBD contained therein;

iii. the net weight;

iv. the expiration date; and

v. any caution statements.

E. Distribution of Marijuana Products to Marijuana Pharmacies

1. The producer shall maintain complete inventory records in the Louisiana medical marijuana tracking system (LMMTS), as required and delineated in rules promulgated by LDAF.

2. The producer shall maintain comprehensive records in LMMTS of all marijuana products distributed to the marijuana pharmacies, whether by transport and delivery to the pharmacy or by transfer to the agent of the pharmacy at the production facility.

3. In the event the producer delivers the products to the pharmacy, such activities must be in compliance with the rules for that activity promulgated by LDAF.

4. In the event the pharmacy elects to send an agent to the production facility to retrieve products ordered by the pharmacy, the personnel at the production facility shall verify the identity and credentials of the pharmacy's agent before releasing the products to the agent.

a. The producer shall provide a copy of the transport manifest generated by LMMTS, which shall contain the following information:

i. the name and address of the producer selling the product;

ii. the name and address of the pharmacy purchasing the product;

iii. the name and quantity (by weight or unit) of marijuana products included in the delivery;

iv. the date of transport and time of departure from the production facility;

v. the make, model, and license plate number of the delivery vehicle;

vi. the date and time of arrival at the pharmacy; and

vii. the name and signature of the pharmacy's agent.

b. The pharmacy's agent shall compare the transport manifest to the products transferred to his possession, and when correct, shall return a signed copy of the manifest to the producer before departing from the production facility.

c. The pharmacy's agent shall place the products in a locked, safe, and secure storage compartment that is part of the motor vehicle, or in the alternative, in a locked storage container that has a separate key or combination pad, and further, the product shall not visible or recognizable from outside the vehicle, and further, the vehicle shall not bear the name of the pharmacy or any markings to indicate the vehicle contains marijuana.

d. The pharmacy's agent shall maintain physical control of the vehicle at all times during the transport, and shall not leave the vehicle unattended at any time.

e. The pharmacy's agent shall have access to a secure form of communication with the pharmacy as well as the ability to contact law enforcement through the 911 emergency system.

f. Upon arrival at the pharmacy, the pharmacy's agent shall deliver the product to a pharmacist for verification of receipt; the pharmacist shall time, date, and sign the delivery manifest.

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), amended LR 46:568 (April 2020), LR 46:1227 (September 2020), LR 47:590 (May 2021), LR 48:1902 (July 2022).

§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 deemed guilty of operating a pharmacy without a valid permit, in violation of R.S. 37:1221.

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. The board shall not have more than 10 active marijuana pharmacy permits at any given time. To facilitate compliance with that legislative restriction, the board recognizes the nine regions previously declared by the Department of Health, to wit:

1. metropolitan, composed of the parishes of Jefferson, Orleans, Plaquemines, and St. Bernard;

2. capitol, composed of the parishes of Ascension, East Baton Rouge, East Feliciana, Iberville, Pointe Coupee, West Baton Rouge, and West Feliciana;

3. Teche, composed of the parishes of Assumption, Lafourche, St. Charles, St. James, St. John, St. Mary, and Terrebonne;

4. Acadian, composed of the parishes of Acadia, Evangeline, Iberia, Lafayette, St. Landry, St. Martin, and Vermilion;

5. southwest, composed of the parishes of Allen, Beauregard, Calcasieu, Cameron, and Jefferson Davis;

6. central, composed of the parishes of Avoyelles, Catahoula, Concordia, Grant, LaSalle, Rapides, Vernon, and Winn;

7. northwest, composed of the parishes of Bienville, Bossier, Caddo, Claiborne, DeSoto, Natchitoches, Red River, Sabine, and Webster;

8. northeast, composed of the parishes of Caldwell, East Carroll, Franklin, Jackson, Lincoln, Madison, Morehouse, Ouachita, Richland, Tensas, Union, and West Carroll; and

9. southeast, composed of the parishes of Livingston, St. Helena, St. Tammany, Tangipahoa, and Washington.

H. To achieve an equitable distribution of the marijuana pharmacy permits across the state, the board shall reserve one marijuana pharmacy permit for each of the nine regions identified above. In the event the board is convinced of the need for a second permit in one region, it may issue that permit following the procedures identified in this Subchapter. Further expansion will require a legislative amendment of the original restriction.

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).

§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;

c. 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;

d. 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. a blueprint of the proposed marijuana pharmacy which shall, at a minimum, show and identify:

i. the square footage of the area which will constitute the prescription department;

ii. the square footage of the overall marijuana pharmacy;

iii. the square footage and location of areas used as storerooms or stockrooms;

iv. the size of the counter that will be used for the dispensing and sale of marijuana;

v. the location of the marijuana pharmacy sink and refrigerator, if any;

vi. the location of all approved safes and vaults that will be used to store marijuana;

vii. the location of the toilet facilities;

viii. the location of the break room and location of lockers for personal belongings;

ix. the location and size of the patient counseling area(s);

x. the location(s) where any other products or services will be offered; and

xi. the location of all areas that may contain marijuana showing the location of walls, partitions, counters, and all areas of ingress and egress;

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. The applicant shall supplement the application form with sufficient documentation of the applicant's financial capacity to properly operate a marijuana pharmacy, including but not limited to, evidence of his escrow account, letter of credit, or surety bond of at least $100,000 in a financial institution headquartered in Louisiana.

a. The pharmacy's $100,000 escrow account, letter of credit, or surety bond shall be payable to the board in the event the board determines after a due process hearing that the pharmacy has failed to timely and successfully complete the construction of the pharmacy or to operate such pharmacy in compliance with the provisions of this Subchapter.

b. The board shall permit the pharmacy's escrow account, letter of credit, or surety bond to be reduced by $25,000 upon the successful achievement of each of the following milestones:

i. a determination by the board that the pharmacy is fully operational and able to commence and has begun dispensing of marijuana as provided in this Subchapter;

ii. a determination by the board that the pharmacy remained operational and without substantial interruption

and without any violation of law or regulation for a one-year period; and

iii. a determination by the board that the pharmacy remained operational and without substantial interruption and without any violation of law or regulation for a second one-year period.

iv. the pharmacy shall maintain the escrow account, letter of credit, or surety bond for a minimum of $25,000 for the remainder of its operation.

c. In the event a pharmacy voluntarily chooses not to renew the pharmacy permit and follows proper closure procedures, the board shall extinguish the obligations under the escrow account, letter of credit, or surety bond at the end of the permit's term.

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. The board may verify information contained in each application and accompanying documentation in order to assess the applicant's character and fitness to operate a marijuana pharmacy. The board may verify the information and assess the applicant's character and fitness by, among other actions:

a. contacting the applicant by telephone, electronic mail, mail, or such other means as is reasonable under the circumstances;

b. conducting one or more on-site visits of the location for the proposed marijuana pharmacy, or other pharmacies associated with the applicant or any of the applicant's owners;

c. conducting background checks or contacting references of the applicant, its managing officer, any of the corporate officers, or any shareholder, as well as the pharmacist-in-charge;

d. contacting state regulators in any other states where the applicant, the applicant's owners or corporate officers, or its pharmacist-in-charge are engaged in, or have sought to be engaged in, any aspect of that state's medical marijuana program; or

e. requiring a personal meeting with the owner's managing officer and the pharmacist-in-charge and the submission of additional information or documents.

13. The application shall be accompanied by payment of the permit fees and administrative hearing fee authorized by R.S. 37:1184 and 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

c. 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 pharmacy 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 R.S. 37:1184 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(12).

5. An application for the late renewal of an expired (lapsed) marijuana pharmacy permit that is received in the board office no later than 30 days after the expiration date of the permit may be processed by the board staff, provided the appropriate delinquent fee authorized in R.S. 37:1184 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 R.S. 37:1184 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. A duplicate or replacement permit shall be issued upon the written request of the licensee and payment of the fee authorized in R.S. 37:1184. A duplicate or replacement license shall not serve or be used as an additional or second license.

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, or 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 R.S. 37:1184. 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).

§2449. Marijuana Pharmacy Personnel

A. No person shall be employed by, or affiliated with, a marijuana pharmacy prior to their eighteenth birthday.

B.1. The PIC shall insure and document the initial and continuing competency of the entire professional staff to provide the pharmacy care services rendered at the marijuana pharmacy. At a minimum, the PIC shall provide access to education and training in the following domains:

a. policies and procedures of the pharmacy, especially those relating to the tasks and functions that employee is expected to perform;

b. professional conduct, ethics, and patient confidentiality; and

c. developments in the therapeutic use of marijuana.

2. Further, the PIC shall document such education and training, provide such records to the board when requested, and retain such records for at least two years after the employee disassociates with the pharmacy.

C. The PIC shall comply with the professional supervision rules and ratios found in Chapter 7 (pharmacy interns) and Chapter 9 (pharmacy technicians) of this Part.

D. In addition to the scope of practice limitations found in Chapter 9 of this Part, pharmacy technicians practicing in a marijuana pharmacy shall not:

1. consult with a patient or the patient's caregiver regarding marijuana or other drugs, either before or after marijuana has been dispensed, or regarding any medical information contained in a patient medication record;

2. consult with the physician who issued the recommendation/prescription/order for marijuana to the patient, or the physician's agent, regarding a patient or any medical information pertaining to the patient's marijuana or any other drug the patient may be taking;

3. interpret the patient's clinical data or provide medical advice;

4. perform professional consultations with physicians, nurses, or other health care professionals or their authorized agents; or

5. determine whether a different brand or formulation of marijuana should be dispensed for the marijuana product or formulation recommended/prescribed/ordered by the physician or requested by the patient or his caregiver.

AUHORITY 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).

§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.

1. 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. The marijuana pharmacy shall establish, implement and adhere to a written alcohol-free, drug-free and smoke-free work place policy, which shall be available to the board upon request.

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. Upon delivery, the marijuana shall immediately be placed in an approved safe or approved vault within the pharmacy where marijuana is stored.

N. No marijuana pharmacy shall acquire, possess or dispense any controlled substance other than medical marijuana products authorized by R.S. 40:1046.

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 a physician 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. 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. At the patient or caregiver's request, the marijuana pharmacy may deliver or facilitate the delivery of a dispensed marijuana product to the patient's location. The delivery of a dispensed marijuana product is subject to the following requirements:

1. The marijuana pharmacy shall not deliver or facilitate the delivery of a marijuana product to a location outside the state.

2. The marijuana pharmacy shall ensure the physical integrity and security of the marijuana product while in transit.

3. 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.

4. 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 federal, 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), amended LR 47:590 (May 2021), LR 48:2103 (August 2022).

§2453. Security Requirements for Marijuana Pharmacies

A. A marijuana pharmacy shall:

1. store all marijuana in an approved safe or vault, as defined in this Subchapter, and in such a manner as to prevent diversion, theft, or loss;

2. maintain all marijuana in a secure area or location accessible only to specifically authorized employees, which shall include only the minimum number of employees essential for efficient operation;

3. 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;

4. keep all approved safes and vaults securely locked and protected from entry, except for the actual time required to remove or replace marijuana, provided that during hours of operation the pharmacist-in-charge may authorize the placement of a limited quantity of dispensing stock outside such safes or vaults but within the secure prescription department.

5. keep all locks and security equipment in good working order;

6. not allow keys to be left in the locks and not store or place keys in a location accessible to persons other than specifically authorized employees;

7. not allow other security measures, such as combination numbers, passwords or electronic or biometric security systems, to be accessible to persons other than specifically authorized employees;

8. keep the pharmacy securely locked and protected from entry by unauthorized employees;

9. keep the outside perimeter of the pharmacy premises well-lit; and

10. post a sign at all entry ways into any area of the pharmacy containing marijuana, including a room with an approved safe or vault, which sign shall be a minimum of 12 inches in height and 12 inches in width which shall state: "Do Not Enter—Limited Access Area—Access Limited to Authorized Employees Only" in lettering no smaller than 1/2 inch in height.

B. All pharmacies shall have an adequate security system to prevent and detect diversion, theft or loss of marijuana utilizing commercial grade equipment, which shall include at a minimum:

1. a perimeter alarm;

2. motion detector;

3. video cameras in all areas that may contain marijuana and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance. The pharmacy shall direct cameras at all approved safes and vaults, dispensing areas, marijuana sales areas and any other area where marijuana is being stored or handled. At entry and exit points, the pharmacy shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the pharmacy;

4. 24-hour recordings from all video cameras, which the pharmacy shall make available for immediate viewing by the board or its authorized representative upon request and shall retain for at least 30 days. If a pharmacy is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the pharmacy shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmacy that it is not necessary to retain the recording:

a. all video recordings shall allow for the exporting of still images in an industry standard image format, including .jpg, .bmp, and .gif. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A pharmacy shall erase all recordings prior to disposal or sale of the pharmacy;

5. *duress alarm*, which for purposes of this Subsection means a silent security alarm system signal generated by the entry of a designated code in into an arming station in order to signal that the alarm user is being forced to turn off the system;

6. *panic alarm*, which for purposes of this Subsection means an audible security alarm system signal generated by the manual activation of a device intended to signal a life-threatening or emergency situation requiring a law enforcement response;

7. *holdup alarm*, which for purposes of this Subsection means a silent alarm signal generated by the manual activation of a device intended to signal a robbery in progress;

8. *automatic voice dialer*, which for purposes of this Subsection means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety or emergency services agency requesting dispatch;

9. a failure notification system that provides an audible, text or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the pharmacy within five minutes of the failure, either by telephone, email, or text message;

10. the ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);

11. a date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and

12. the ability to remain operational during a power outage.

C. A pharmacy shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations.

1. A pharmacy shall keep all on-site surveillance rooms locked and shall not use such rooms for any other function.

2. A pharmacy shall limit access to surveillance areas to persons that are essential to surveillance operations, law enforcement agencies, security system service employees, and the board's authorized representative.

3. A pharmacy shall make available to the board upon request a current list of authorized employees and service employees that have access to the surveillance room.

D. A pharmacy shall keep all security equipment in good working order and shall test such equipment no less than two times per year.

E. When a pharmacy presents special security issues, such as an extremely large stock of marijuana, exposed handling or unusual vulnerability to, or actual, diversion, theft or loss, the board may require additional safeguards, including but not limited to, a supervised watchman service.

F. Any marijuana not stored in compliance with this Section, or stored at a location other than that for which the pharmacy permit was issued, shall be subject to embargo or seizure by the board.

G. In the event any marijuana pharmacy permit is revoked, suspended, or not renewed, the pharmacy shall dispose of its entire stock of marijuana in accordance with the disposal provisions in this Subchapter.

H. If a pharmacy has provided other safeguards which can be regarded in total as an adequate substitute for some element of protection required of the pharmacy, such added protection may be taken into account by the board in evaluating overall required security measures.

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).

§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. A pharmacy shall notify the board no later than the next business day, followed by written notification no later than 10 business days, of any of the following:

1. an alarm activation or other event that requires response by public safety personnel;

2. a breach of security;

3. the failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and

4. corrective measures taken, if any.

D. A pharmacy shall maintain and shall make available all documentation related to an occurrence that is reportable.

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).

§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.

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, and further, complies with security requirements identified elsewhere in this Subchapter.

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.

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 physician 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 R.S. 40:1046, 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 a physician in possession of a current and unrestricted license to practice medicine from the Louisiana State Board of Medical Examiners as well as a current and unrestricted state controlled substance license with therapeutic marijuana privileges from the board; and

ii. received directly from the physician 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 physician.

b. The request shall disclose the following information at a minimum:

i. name, address, telephone number, and national provider identifier (NPI) number of the physician 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 physician holds a current and unrestricted license to practice medicine issued by the Louisiana State Board of Medical Examiners; and

vii. Signature of the physician 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 physician. 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 physician.

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 physician 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

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 LDAF, 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 physician;

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. 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 grind 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).

§2459. Advertising

A. The marijuana pharmacy shall not advertise through any public medium, including but not limited to newspapers, billboards, television, radio, internet, social media, or any other means designed to market its products to the general public.

B. The marijuana pharmacy may market its products through direct mail, brochures, or other means to Louisiana-licensed physicians, but only when such advertising is directed solely to the practitioner and is not available to the general public.

C. Any advertisement permitted in Subsection B of this Section shall not:

1. make any deceptive, false, or misleading assertions or statements regarding any product; or

2. assert that its products are safe because they are regulated by LDAF or the board. The pharmacy may advertise that its products have been tested by an approved laboratory, but shall not assert that its products are safe because they are tested by an approved laboratory.

D. The marijuana pharmacy may attach a maximum of two separate signs to the exterior of the building which identify the business by its business or trade name, provided that neither sign exceeds the size limit of 1,600 square inches.

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).

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. Prescription drugs or devices shall be stored in a permitted pharmacy under the immediate control and responsibility of a pharmacist.

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 Federal Food, Drug, and 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.

§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 21 CFR §1317 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 29:2101 (October 2003), effective January 1, 2004, amended by the Department of Health, Board of Pharmacy, LR 46:793 (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 name of the study sponsor;

3. protocol number;

4. identification of 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 to 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 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 transmitted in electronic form.

Practice Affiliation—a practice relationship, collaboration, or practice under the supervision of a physician licensed to practice medicine.

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. Requirements. A prescription shall contain the following data elements:

1. prescriber's name, licensure designation, address, telephone number, and if for a controlled substance, the Drug Enforcement Administration (DEA) registration number;

2. patient's name, and if for a controlled substance, address;

3. date prescription issued by the prescriber;

4. name of drug or device, and if applicable, strength, and quantity to be dispensed;

5. directions for use;

6. signature of prescriber; and

7. refill instructions, if any. In the absence of refill instructions on the original prescription, the prescription shall not be refilled.

C. Written Prescriptions. A written prescription shall conform to the following format:

1. The prescription form shall be of a size not less than 4 inches by 5 inches, and shall bear a single printed signature line.

2. 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 authorizing prescriber's printed name.

3. No prescription form shall contain more than four prescription drug orders. Each prescription drug order recorded on the form shall provide the following:

a. check box labeled "Dispense as Written", or "DAW", or both; and

b. the number of refills, if any.

4. 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.

5. Receipt via Facsimile

a. 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.

b. 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.

6. Chart orders and forms used by pharmacists to record telephoned or transferred prescriptions are exempt from the format requirements listed above.

D. Oral Prescriptions

1. 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. 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.

E. Electronic Prescriptions

1. 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. Completion of Prescription Orders and Chart Orders. In the event a pharmacist receives a prescription order or chart order lacking certain required information, the pharmacist may consult with the prescriber to clarify the prescriber's intent. Following a consultation with the prescriber and the appropriate documentation thereof on the order:

1. A pharmacist may add the following data elements on the order:

a. patient's address; or

b. drug dosage form.

2. A pharmacist may record changes in the following data elements on the order:

a. patient's address;

b. drug strength;

c. quantity prescribed; or

d. directions for use.

3. A pharmacist shall never add or make changes to the following data elements on the order:

a. patient's name;

b. date of issue;

c. drug name (except for generic interchange as permitted by law); or

d. prescriber signature.

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), amended, LR 46:585 (April 2020), LR 47:1644 (November 2021).

§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 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 21 CFR §1317 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. 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.

B. Refill Requests. Prescription refills authorized by the prescriber shall not be dispensed in the absence of a patient or caregiver's request or approval. 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.

C. Controlled Dangerous Substances

1. The refilling of a prescription for a drug listed in Schedule II is prohibited.

2. 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.

3. A prescription for a drug listed in Schedule V may be refilled if so indicated at the time issued subject to the one-year expiration date of the prescription.

D. 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.

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, LR 33:1133 (June 2007), amended by the Department of Health, Board of Pharmacy, LR 42:1519 (September 2016), amended LR 46:575 (April 2020), LR 47:1644 (November 2021).

§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 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 number 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 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 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.

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, 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), amended 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—an 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 Federal Food, Drug and Cosmetic Act of 1938 (FDCA) as subsequently amended, the current edition of Title 21 of the Code of Federal Regulations (CFR), 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 503A 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 503A of the FDCA and USP chapter 795.

c. The compounding of preparations for veterinary use shall comply with the provisions of section 530 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 other 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 medications 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 applicable 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 R.S. 37:1225, 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.

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 23:1316 (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), amended LR 46:577 (April 2020), amended 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.

1. 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).

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 A*dministration*—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*—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*—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).

Reverse Distribute—to acquire controlled substances from another registrant or law enforcement 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), amended LR 46:793 (June 2020), LR 47:1640 (November 2021), LR 48:494 (March 2022).

§2703. Controlled Substances

A. Classification

1. 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;

b. the drug or other substance has no currently accepted medical use in treatment in the United States; and

c. 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;

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 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;

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 limited psychological or physical dependence relative to the drugs or other substances listed in Schedule IV.

C. Scheduling of Additional Controlled Substances. R.S. 40:963 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 R.S. 40:963.

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;

b. 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 R.S. 40:965, 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 21 CFR 1308.32.

E. Excepted Drugs; Exemption from Certain Requirements. Pursuant to R.S. 40:965, 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 21 CFR 1308.32.

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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2128 (October 2008).

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.

2. 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

1. 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 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 Uniform Controlled Dangerous Substances Law 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, the 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 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 identified at R.S. 37:1184.

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 R.S. 40:972. 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2131 (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

1. 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 findings(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, R.S. 49:950 et seq., with authority to take disciplinary action pursuant to R.S. 40:975.

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

i. 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 10 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 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 R.S. 40:972 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 by the board, 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 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 State 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.

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).

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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2134 (October 2008).

§2715. Physical Security Controls for Non-Practitioners, Narcotic Treatment Programs, and Compounders for Narcotic Treatment Programs

A. Storage Areas

1. 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 man-minutes 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 1/2 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 1 1/2 inch reinforcements every 60 inches;

ii. having a mesh construction with openings of not more than 2 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, non employee 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2135 (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, DEA Form 106, 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2137 (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.

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).

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

1. 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

1. 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

iv. 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2141 (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;

v. 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.

2. 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. Record 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 capable 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, 30 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;

3. 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.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2142 (October 2008), amended by the Department of Health, Board of Pharmacy, LR 46:571 (April 2020), amended 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 §1304.31or 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;

j. losses on reweighing;

k. material used for conversion;

l. 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

1. Reports generally. All reports required by this Subsection shall be filed with the ARCOS Unit, PO 28293, Central Station, Washington, DC 20005 on DEA Form 333, 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;

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; and

6. local trends and other indicators of the diversion potential of the missing controlled substance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:972.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Pharmacy, LR 34:2145 (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 DEA Form 222 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.

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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; or

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. A prescription issued for a schedule III, IV, or V narcotic drug approved by FDA specifically for "detoxification treatment" or "maintenance treatment" must include the identification number issued by the DEA or a written notice stating that the practitioner is acting under the good faith exception of 21 CFR §1301.28(d).

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 hand printed on it, as well as the signature of the physician.

6. An official exempted from registration under 21 CFR §1301.22(c) 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 hand printed 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

i. 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.

3. 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 §1301.28.

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 call back 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;

ii. 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 substances 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), amended LR 47:1645 (November 2021).

§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 remaining portion of a 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.

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 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:

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 §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 substance 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 the 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;

(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;

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 Federal Food, Drug, and Cosmetic Act 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), amended LR 41:685 (April 2015), amended by the Department of Health, Board of Pharmacy, LR 46:577 (April 2020), LR 47:1645 (November 2021), amended 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 21 CFR §1317 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 R.S. 40:988.B and R.S. 40:988.C.

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).

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 retains 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 when in combination with at least 325 milligrams of acetaminophen per dosage unit.

b. naloxone.

c. promethazine when present in oral liquid formulation.

d. 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).

§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 transaction information for review by persons authorized to access such information.

B. The board shall archive all prescription transaction information not available for direct or indirect access.

C. The board shall respond to requests for archived prescription transaction information.

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).

§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 or health information 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 application, 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 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 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 approved by the board, but only in compliance with the provisions of R.S. 40:1007(G).

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 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).

Chapter 30. Pharmacy Benefit Managers

§3003. Pharmacy Benefit Manager Permit

A. A pharmacy benefit manager, as defined at R.S. 40:2863, 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 R.S. 40:2868 in the state or that affects one or more beneficiaries of a pharmacy benefit management plan, as defined at R.S. 40:2863, 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 the 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, 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).

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 health care 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 LR 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, R.S. 37:1161 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 health care 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 health care 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 health care 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 in §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, R.S. 37:1161 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 LR 34:2160 (October 2008).

§3119. Disclosure of Financial Interest

[Name of Pharmacist/Group]
[Address]
[Telephone Number]
DISCLOSURE OF FINANCIAL INTEREST
As Required by R.S. 37:1744 and LAC 46:LIII.613-615

TO:_____
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 when they refer a patient to another health care provider or facility in which the pharmacist has a significant financial interest. [I am/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 extent of which are as follows:

_____
_____

PATIENT ACKNOWLEDGEMENT

I, the above-named patient, or legal representative of such patient, hereby acknowledge receipt, on the date indicated and prior to the described referral, of a copy of the foregoing Disclosure of Financial Interest.

_____
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 (October 2003), effective January 1, 2004, repromulgated LR 34:2160 (October 2008).

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, LR 29:2114 (October 2003), effective January 1, 2004, repromulgated LR 33:1348 (July 2007).